



Maastricht Centre for European Law
Master Working Paper

2018/4

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**The European Chemicals Agency and its
Compliance with the *Meroni* Doctrine**

Do the powers of the European Chemicals Agency go beyond
the scope of what is permissible under the *Meroni* doctrine (as
modified by Case C-270/12)?

Abstract

Agencies form an important part of the EU executive, with their number having increased tremendously over the last 48 years. In that regard, the delegation of powers to agencies has always been a very controversial topic. This controversy mainly results from the case *Meroni v. High Authority* in which the Court seemed to have ruled out the possibility to transfer discretionary powers to agencies and the conflicting practice of transferring an increasing scope of powers to EU agencies. On top of that, the European Court of Justice seems to have broadened the limits governing the delegation of powers to agencies in its more recent judgments in cases such as *ESMA Short Selling* or *Rütgers Germany GmbH and Others v European Chemicals Agency*.

The European Chemicals Agency is indeed one of the agencies that attracted attention due to the broad range of powers it has received, including decision-making ones. An analysis of both the uncertainties surrounding the *Meroni* doctrine in its traditional and updated version, as well as the powers of the ECHA under the REACH, CLP, BP and PIC Regulation, shows that ECHA can indeed be defined as a decision-making agency. More specifically, when testing its powers against the limits established in 1958, certain infringements of the traditional *Meroni* doctrine can be identified. On the contrary, those infringements seem to have been remedied by the Court's judgment in *ESMA Short-Selling*, which can therefore be characterized as having opened the door for the transfer of some degree of discretionary powers to EU agencies.

Table of contents

Maastricht Centre for European Law	1
2018/4	1
List of Abbreviations	5
Introduction	7
Chapter 1: The <i>agencification</i> of the EU executive	11
1.1. Agency creation in the European Union.....	11
1.2. Defining agencies.....	13
1.3 Types of agencies in the European Union	14
1.4. Conclusion	16
Chapter 2: Delegation of powers to agencies	17
2.1. Delegation of powers	17
2.2. <i>Meroni v. High Authority</i> : Limits to the delegation of powers to agencies	19
2.3. The <i>ESMA Short-selling Case</i>	22
2.4. A gradual drift away from the strict <i>Meroni</i> requirements?	24
2.4. Conclusion	25
Chapter 3: Delegation of powers to the European Chemicals Agency	27
3.1. The EU's approach to chemicals.....	28
3.1.1. Regulation 1907/2006: Registration, Evaluation, Authorisation and Restriction of Chemicals.....	29
3.1.2. Regulation 1272/2008: Classification, Labelling and Packaging of Substances and Mixtures	32
3.1.3. Regulation 528/2012: Biocidal Products.....	33
3.1.4. Regulation No 649/2012: Export and Import of Hazardous Chemicals....	34
3.2. The organizational structure of the ECHA.....	34
3.3. The tasks and powers of the ECHA	37
3.3.1. The ECHA as information-provider.....	38
3.3.2. The ECHA as advisor	39
3.3.3. The ECHA as administrator and coordinator	41
3.3.4. The ECHA as decision-maker	42
3.4. Conclusion	47
Chapter 4: The European Chemicals Agency and the anti-delegation doctrine: an analysis	49
4.1. The scope of the delegated powers	49
4.2. The control of the Agency	58
4.3. Conclusion	61

Conclusion **63**

Bibliography..... **66**

- 1. Case Law 66
- 2. Books and Book Chapters 66
- 3. Journal Articles and Working Papers 68
- 4. Policy Documents 71
- 5. Other Sources (Websites, Reports, Conference Papers, Etc.) 72

List of Abbreviations

AG	Advocate General
AS	Active Substance
BSE	Bovine Spongiform Encephalopathy
BoA	Board of Appeal
BP	Biocidal Product
BP Regulation	Biocidal Products Regulation
CEDEFOP	Centre for the Development of Vocational Training
CJEU	Court of Justice of the European Union
CLP Regulation	Regulation on Classification, Labelling and Packaging of Substances and Mixtures
CoRoAP	Community Rolling Action Plan
CVPO	Community Plant Variety Office
EBA	European Banking Authority
ECHA	European Chemicals Agency
ECSC	European Coal and Steel Community
ECSC T	Treaty establishing the European Coal and Steel Community
EIOPA	European Insurance and Occupational Pensions Authority
ESMA	European Securities and Markets Authority
EU	European Union
EUROFUND	European Foundation for the Improvement of Living and Working Conditions
MSC	Member State Committee
PIC Regulation	Prior Informed Consent Regulation
PPORD	Product or Process Oriented Research Development

REACH Regulation	Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals
SVHC	Substances of Very High Concern
TFEU	Treaty on the Functioning of the European Union

Introduction

Agencies are part and parcel of the European Union executive.¹ With the first EU agency creation dating back already to the 1970s,² they are nowadays largely accepted as forming an integral part of the European Union and are sometimes even referred to as the '(n)ew (p)aradigm of European Governance'.³ However, despite their importance for a smooth functioning of the EU, the delegation of powers to agencies has been controversial from the very beginning onwards. This results mainly from the fact that, already in 1958, the Court, by its judgment in *Meroni v. High Authority* (hereinafter *Meroni*), severely limited the possibility of transferring powers to agencies.⁴ More specifically, the Court ruled that agencies were only allowed to carry out 'clearly defined executive' tasks that would be subject to strict review by the delegating authority, and thereby formally took away the possibility of transferring discretionary powers to those independent bodies.⁵ Although, meanwhile, a new and more relaxed stance towards the delegation of powers to agencies might be deduced from the *United Kingdom v. Council and European Parliament* judgment (hereinafter *ESMA Short-selling*), legally speaking, the *Meroni* limits still constitute good law.⁶

Strangely enough, in defiance of the continuous reference to the *Meroni* requirements by both academics and judges when it comes to the delegation of powers to agencies, theory and practice seem to depart considerably from each other.⁷ In fact, over the years, along with the *agencification* of the EU executive, more and more powers have been transferred to EU agencies, to the extent that, nowadays, besides having advisory, coordinating and informative powers, some of them have even been

¹ Ellen Vos, 'EU Agencies on the Move: Challenges Ahead' (2016) SIEPS Working Paper, 2 (forthcoming).

² Ellen Vos, 'European Agencies and the Composite EU Executive' in Michelle Everson, Cosimo Monda and Ellen Vos (eds), *European Agencies in between Institutions and Member States* (Kluwer Law International 2014), 11.

³ Damien Geradin, Rodolphe Munoz and Nicolas Petit, *Regulation through Agencies in the EU: A New Paradigm of European Governance* (Edward Elgar Publishing 2005); Michelle Everson, Cosimo Monda and Ellen Vos, 'European Agencies in between Institutions and Member States' in Michelle Everson, Cosimo Monda and Ellen Vos (eds), *European Agencies in between Institutions and Member States* (Kluwer Law International 2014), 3.

⁴ Case 9/56 *Meroni & Co. Industrie Metallurgische S.P.A. v. High Authority* [1957–1958] ECLI:EU:C:1958:7, 152.

⁵ *ibid.*

⁶ C-270/12 *The United Kingdom v. Council and European Parliament* [2014] ECLI:EU:C:2014:18.

This is why the *Meroni* doctrine will still be referred to as the reference norm in the course of this Thesis. However, next to that, the possible changes the *ESMA* judgment might bring about in the future will not be neglected.

⁷ Merijn Chamon, 'EU Agencies: Does the Meroni Doctrine Make Sense?' (2010) 17(1) *Maastricht Journal of European and Comparative Law* 281, 291; Marta Simoncini, 'The Erosion of the Meroni Doctrine: The Case of the European Aviation Safety Agency' (2015) 21(2) *European Public Law* 309, 317-318.

allowed to carry out decision-making tasks.⁸ In light of the just outlined *Meroni* requirements, this has raised a lot of criticism.⁹

One of the agencies that was given the power to take binding decisions with third party effect is the European Chemicals Agency (hereinafter ECHA or Agency).¹⁰ The European Chemicals Agency is one of the biggest agencies of the EU, with its main task being the implementation of the EU's chemicals policy.¹¹ More specifically, ECHA has been conferred upon tasks in the framework of four different regulations, under three of which, namely the REACH, CLP and BP Regulation, it has been given the power to take decisions to a certain extent.¹² What is especially striking when it comes to the ECHA is that the General Court, in among others, *Rütgers Germany GmbH and Others v European Chemicals Agency*, ruled that the agency 'has a broad discretion in a sphere which entails political, economic and social choices on its part, and in which it is called upon to undertake complex assessments'.¹³ This statement is quite astonishing because it seems to completely contradict what has been ruled in both *Meroni* and even in *ESMA*. The wide range of powers the ECHA possesses taken in conjunction with the discrepancies that exist with regard to the scope of power that can legally be delegated to agencies justifies the scope of the present Thesis, which deals with the powers the European Chemicals Agency enjoys in practice and their compliance with the non-delegation doctrine. It tries to answer the following question: *Do the powers of the European Chemicals Agency go beyond the scope of what is permissible under the Meroni doctrine (as modified by Case C-270/12)?* In the course of answering this question several sub-problems such as the definition of concepts such as 'agency' or 'delegation', the exact nature of the ECHA's powers, the

⁸ Merijn Chamon, 'EU Agencies between Meroni and Romano or the Devil and the Deep Blue Sea' (2011) 48(4) *Common Market Law Review* 1055, 1055-1056; Miroslava Scholten and Marloes van Rijsbergen, 'The ESMA-Short Selling Case: Erecting a New Delegation Doctrine in the EU upon the *Meroni-Romano* Remnants' (2014) 41(4) *Legal Issues of Economic Integration* 389, 389.

⁹ See for example: Hedwig CH Hofmann and Alexander H Türk, 'Implementing Policy' in Hedwig CH Hofmann and Alexander H Türk (eds), *EU Administrative Governance* (Edward Elgar Publishing 2006), 89; Merijn Chamon, 'EU Agencies: Does the Meroni Doctrine Make Sense?' (2010) 17(1) *Maastricht Journal of European and Comparative Law* 281, 291; Michelle Everson, 'European Agencies: Barely Legal?' in Michelle Everson, Cosimo Monda and Ellen Vos, *European Agencies in Between Institutions and Member States* (Kluwer Law International 2014).

¹⁰ Ellen Vos, 'EU Agencies on the Move: Challenges Ahead' (2016) SIEPS Working Paper, 12 (forthcoming).

¹¹ Sami Andoura and Peter Timmerman, 'Governance of the EU: The Reform Debate on European Agencies Reignited' (2008) EPIN Working Paper 19/2008, 32 <<http://aei.pitt.edu/11474/>> last accessed 24 August 2017.

¹² See section 3.3.4. for an elaboration of ECHA's decision-making powers.

¹³ This case concerned ECHA's powers to add certain chemicals to a candidate list for authorisation under Art. 59 of the REACH Regulation.

Case T-96/10 *Rütgers Germany GmbH v. ECHA* [2013] ECLI:EU:T:2013:109, para 134.

specificities of cases such as *Rütgers*, as well as the potential added value of the judgment in *ESMA Short-selling* will be elaborated on.

In the following, the above-mentioned discrepancies will be analysed. To this end, chapter one provides some background information about the ongoing *agencification* of the EU executive and the rationales behind the ‘mushrooming’ of agencies at EU level.¹⁴ In that regard, the lack of an official definition of what constitutes an agency will be addressed. Moreover, it will be acknowledged that the scope of agencies’ powers has increased over time, making it possible to classify them as either advisory, pre-decision-making, decision-making or regulatory agencies respectively. Chapter two provides an analysis of the ‘anti-’ or ‘limited-delegation’ doctrine as developed in *Meroni v. High Authority* and modified in *ESMA Short-selling*. To this end, the delegation of powers to agencies will be addressed more generally first, before then turning to the requirements developed in the *Meroni* and the *ESMA Short-selling* case. The added value, if any, of this latter case will be addressed in section 2.4. In that regard, especially two different aspects will be highlighted, namely the importance of control mechanisms and the diverging settings. Next, chapter three introduces the European Chemicals Agency. In order to get a clear picture of the functioning of the ECHA and the context surrounding the establishment of the Agency, an explanation of the different regulations that ECHA assumes powers in, as well as its organizational structure is necessary. Next, the different powers of the ECHA will be explained, on the basis of a distinction of different functions assumed by the Agency, namely its role as information-provider, advisor, manager and decision-maker respectively. A special focus will be on the controversial decision-making powers, which will, in conjunction with the conclusion drawn as to ECHA’s nature in light of the agency classification criteria provided for in section 1.3, serve as a basis for the compliance analysis in chapter four. In turn, chapter four finally analyses the compatibility of ECHA’s powers, with the *Meroni* doctrine. This analysis will be conducted in two different stages. Firstly, the scope of the powers enjoyed will be tested against the requirements established in the *Meroni* and *ESMA* cases. Secondly, the same will be done with the requirement of Agency control. In the end, it will be concluded whether the ECHA indeed enjoys

¹⁴ Michelle Everson and Ellen Vos, ‘European Agencies: What about the Institutional Balance?’ (2014) Maastricht Faculty of Law Working Paper 4/2014, 4 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2467469> last accessed 24 August 2017.

powers that go beyond the scope of the traditional *Meroni* doctrine and whether the judgment in *ESMA Short-selling* would lead to a different outcome in that regard.

Chapter 1: The *agencification* of the EU executive

Before addressing the limits to the delegation of powers to agencies as well as the observance of those limits in the specific case of the European Chemicals Agency in the upcoming chapters, this chapter will provide the reader with some background information about the practice of establishing agencies in the European Union, the motives underlying their creation, their main characteristics and the range of tasks exercised by them.

1.1. Agency creation in the European Union

The creation of agencies has been an established practice at national level for a long time.¹⁵ It did thus not come as a big surprise when the EU executive started following this trend. The *agencification* of the EU executive took off in the 1970s and has been ongoing ever since,¹⁶ to the extent that nowadays 34 decentralised agencies can be counted.¹⁷ In general it is said that agencies have been created in three waves.¹⁸ The first to be established in 1975 were the EUROFUND¹⁹ and the CEDEFOP²⁰.²¹ Subsequently, in the early 1990s, in a second wave of agency creation, bodies such as the European Medicines Agency²² or the European Environmental Agency²³ were set up.²⁴ Finally, after resort to agencies had been formally approved by the Commission in its White Paper of 2001, another set of EU agencies was

¹⁵ Morten Egeberg and Jarle Trondal, 'Agencification of the European Union Administration: Connecting the Dots' (2016) TARN Working Paper 1/2016, 1 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2754716> last accessed 24 August 2017.

¹⁶ Jørgen Grønnegaard Christensen and Vibeke Lehmann Nielsen, 'Administrative Capacity, Structural Choice and the Creation of EU Agencies' (2010) 17(2) *Journal of European Public Policy* 176, 176-177.

¹⁷ Indeed, if agencies are referred to in this Thesis, what is meant are decentralised agencies. Executive agencies will not be discussed.

Full list of decentralised agencies to be found at: – –, <https://europa.eu/european-union/about-eu/agencies/decentralised-agencies_en> last accessed 24 August 2017.

¹⁸ See for example: Jarle Trondal and Lene Jeppesen, 'Images of Agency Governance in the European Union' (2008) 31(3) *West European Politics* 417, 419; Michelle Everson and Ellen Vos, 'European Agencies: What about the Institutional Balance?' (2014) Maastricht Faculty of Law Working Paper 4/2014, 6 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2467469> last accessed 24 August 2017; Morten Egeberg and Jarle Trondal, 'Agencification of the European Union Administration: Connecting the Dots' (2016) TARN Working Paper 1/2016, 1 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2754716> last accessed 24 August 2017.

¹⁹ European Foundation for the Improvement of Living and Working Conditions; Council Regulation (EEC) 1365/75 on the creation of a European Foundation for the Improvement of Living and Working Conditions [1975] OJ L 139/1.

²⁰ Centre for the Development of Vocational Training; Council Regulation (EEC) 337/75 on establishing a European Centre for the Development of Vocational Training [1975] OJ L 39/1.

²¹ Ellen Vos, 'EU Agencies on the Move: Challenges Ahead' (2016) SIEPS Working Paper, 3 (forthcoming).

²² Council Regulation (EEC) 2308/93 amending Regulation (EEC) 1543/93 introducing a countervailing charge on fresh lemons originating in Argentina [1993] OJ L 208/33.

²³ Council Regulation (EEC) 1210/90 on the establishment of the European Environmental Agency and the European Environment Information and Observation Network [1990] OJ L 120/1.

²⁴ Ellen Vos, 'EU Agencies on the Move: Challenges Ahead' (2016) SIEPS Working Paper, 2 (forthcoming).

eventually created.²⁵ This third wave resulted in the establishment of among others the European Food Safety Authority²⁶ or the new European Supervisory Authorities in the financial sector (EBA, ESMA, EIOPA),²⁷ both of which are non-majoritarian bodies that were created as a reaction to the BSE crisis and the financial crisis respectively.²⁸ This is however not to say that the only reason for establishing agencies lies in its suitability to regain trust in the Union's regulatory system after the occurrence of crises.²⁹ On the contrary, several rationales underlying the continuous creation of agencies have been identified over the years. Benefits of agency creation are for example the reduction of political influence in and the amelioration of technical expert decision-making,³⁰ the possibility for the Commission to focus on its main and most important tasks with the result that the Union's executive system becomes more efficient,³¹ or the enhancement of the cooperation between the EU and the Member States, which is thought to result in more uniformity when implementing EU law,³² to only mention a few. Indeed all of those preceding reasons played some role in the establishment of the ECHA.³³ On top of that, in reality, a widespread though not so glorious reason for creating agencies is the simple fact that, despite the need for transferring more powers to the Commission,

²⁵ Commission (EC), 'European Governance – A White Paper' (White Paper) COM (2001) 428 final, 24; Ellen Vos, 'EU Agencies on the Move: Challenges Ahead' (2016) SIEPS Working Paper, 4 (forthcoming).

²⁶ Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L 31/1.

²⁷ Regulation (EU) 1093/2010 establishing a European Supervisory Authority (European Banking Authority) amending Decision 716/2009/EC and repealing Commission Decision 2009/78/EC [2010] OJ L 331/12; Regulation (EU) 1094/2010 establishing a European Supervisory Authority (European Insurance and Occupational Pensions Authority) amending Decision 716/2009/EC and repealing Commission Decision 2009/79/EC [2010] OJ L 331/48; Regulation (EU) 1095/2010 establishing a European Supervisory Authority (European Securities and Markets Authority) amending Decision 716/2009/EC and repealing Commission Decision 2009/77/EC [2010] OJ L 331/84.

²⁸ Michelle Everson and Ellen Vos, 'European Agencies: What about the Institutional Balance?' (2014) Maastricht Faculty of Law Working Paper 4/2014, 6-7 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2467469> last accessed 24 August 2017; René Smits, 'The Crisis Response in Europe's Economic and Monetary Union: Overview of Legal Developments' (2015) 38(4) *Fordham International Law Journal* 1135, 1177; Morten Egeberg and Jarle Trondal, 'Agencification of the European Union Administration: Connecting the Dots' (2016) TARN Working Paper 1/2016, 4 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2754716> last accessed 24 August 2017.

²⁹ *ibid.*

³⁰ Herwig CH Hofmann, 'Agency Design in the European Union' (2010) 28(2) *Windsor Yearbook of Access to Justice* 309, 311-312.

³¹ Michaela Wittinger, '„Europäische Satelliten“: Anmerkungen zum Europäischen Agentur(un)wesen und zur Vereinbarkeit Europäischer Agenturen mit dem Gemeinschaftsrecht' (2008) 5 *EuR* 609, 618; Morten Egeberg and Jarle Trondal, 'Agencification of the European Union Administration: Connecting the Dots' (2016) TARN Working Paper 1/2016, 4 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2754716> last accessed 24 August 2017; Ellen Vos, 'EU Agencies on the Move: Challenges Ahead' (2016) SIEPS Working Paper, 5-6 (forthcoming).

³² Michaela Wittinger, '„Europäische Satelliten“: Anmerkungen zum Europäischen Agentur(un)wesen und zur Vereinbarkeit Europäischer Agenturen mit dem Gemeinschaftsrecht' (2008) 5 *EuR* 609, 618; Michelle Everson and Ellen Vos, 'European Agencies: What about the Institutional Balance?' (2014) Maastricht Faculty of Law Working Paper 4/2014, 3 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2467469> last accessed 24 August 2017.

³³ Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Regulation (EEC) 793/93 and Commission Regulation (EC) 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [2006] OJ L 396/1 (hereinafter REACH Regulation); Björn Rögnvaldsson Þór and Konstantinos G Margaritis, 'European Chemicals Agency and Good Governance' (2012) Human Rights and Human Welfare Working Papers 69/2012, 7 <www.du.edu/korbel/hrhw/workingpapers/2012/69-rognvaldsson-2012.pdf> last accessed 24 August 2017.

Member States are often hesitant to do so. In such situations, empowering independent agencies that operate at arm's length from the Commission is often conceived as the best possible compromise.³⁴

1.2. Defining agencies

Despite the creation of agencies at EU level being an established practice by now, there is still no official definition of what features a body needs to have in order to be classified as an agency.³⁵ On the contrary, the characterization of agencies seems to have evolved over the years and even the Commission's understanding of it has changed over time. In the beginning, the Commission distinguished only between simple executive agencies on the one hand and regulatory agencies on the other hand.³⁶ In its Draft Inter-institutional Agreement of 2005, it defined a regulatory agency as:

'(...) an independent legal entity created by the legislator in order to help regulate a particular sector at European level and help implement and particular Community Policy'.³⁷

In that regard, the term 'regulatory agency' has been often criticised, because in fact a US-type of 'regulatory agency' that has the power to adopt 'rules of general application' does not exist in the EU.³⁸ Therefore, in a next step, in light of the failure to adopt the proposed Inter-institutional Agreement, the Commission seems to have become partly aware of the misleading picture the denomination 'European Regulatory Agency' brought along, and started referring to regulatory agencies as 'traditional' or 'decentralised' ones.³⁹ According to the Commission, those agencies are characterised by the fact that they are created by means of a sector specific regulation,

³⁴ DR Keleman, 'The Politics of "Eurocratic" Structure and the New European Agencies' (2002) 25(4) *West European Politics* 93, 95; Herwig CH Hofmann, 'Agency Design in the European Union' (2010) 28(2) *Windsor Yearbook of Access to Justice* 309, 311-312.

³⁵ Merijn Chamon, 'EU Agencies: Does the Meroni Doctrine Make Sense?' (2010) 17(1) *Maastricht Journal of European and Comparative Law* 281, 282-283.

³⁶ Commission (EC), 'Draft Interinstitutional Agreement on the Operating Framework for the European Regulatory Agencies' (Draft Interinstitutional Agreement) COM (2005) 59 final.

³⁷ *ibid.*, 5.

³⁸ Stefan Griller and Andreas Orator, 'Everything under Control? The "Way Forward" for European Agencies in the Footsteps of the Meroni Doctrine' (2010) 35(1) *European Law Review* 3, 7.

³⁹ Commission (EC), 'European Agencies – The Way Forward' (Communication) COM (2008) 135 final, 4.

by their independence, their own legal personality as well as their budget being financed by the EU in most cases.⁴⁰ Meanwhile, the Commission also adopted a Common Approach, which provides for a uniform framework for the creation and functioning of EU agencies.⁴¹

Next to this, when comparing different elaborations provided for in literature, it becomes apparent that a definition proposed by Griller and Orator in 2010 seems to capture the essence of what characterises agencies nowadays very well, because it includes most of the features that were cited by the Commission as being essential but at the same time avoids the use of the confusing terminology of ‘regulatory agency’.⁴² It states that an agency is a

(...) relatively independent, permanent body with legal personality, emanating from secondary Union law and charged with specific tasks. Moreover, most European agencies share a certain structure and composition. They follow a “dual approach”, comprising an executive director and a management board.⁴³

1.3 Types of agencies in the European Union

As the classification provided for by the Commission is in general rather unsatisfactory and misleading when it comes to what it calls ‘regulatory’ or ‘decentralised’ agencies, it has been decided to go beyond this modest division. In light of the objective pursued by this Thesis, namely delineating the broad powers of the European Chemicals Agency to an extent that makes it possible to establish whether the constitutional non-delegation requirements as laid down in the *Meroni* case are complied with, it is most suitable to classify the variety of agencies according to the prerogatives delegated to them, with a special focus on the scope of those prerogatives.⁴⁴ In that regard, an increase of powers has been observed over the

⁴⁰ *ibid* 4.

⁴¹ European Parliament, Council of the EU and European Commission, ‘Joint Statement on decentralised agencies and Common Approach’ (Joint Statement) 19/07/2012.

⁴² Commission (EC), ‘European Agencies – The Way Forward’ (Communication) COM (2008) 135 final, 4.

⁴³ Stefan Griller and Andreas Orator, ‘Everything under Control? The “Way Forward” for European Agencies in the Footsteps of the Meroni Doctrine’ (2010) 35(1) *European Law Review* 3, 6.

⁴⁴ Damien Geradin and Nicolas Petit, ‘The Development of Agencies at EU and National Levels: Conceptual Analysis and Proposals for Reform’ (2004) Jean Monnet Working Paper 1/2004, 48 <www.jeanmonnetprogram.org/archive/papers/04/040101.html> last accessed 24 August 2017.

years. Whereas, as mentioned above, in the beginning, agencies only had very modest coordinating, information gathering and expert providing tasks, over time, a broader range of powers has been delegated to them, to the extent that it is nowadays possible to distinguish between four different types of agencies.⁴⁵ The first category of agencies is made up of so-called 'ordinary agencies', whose tasks can vary from observing to providing information or networking. Though the precise scope of their powers can vary, what all of these first category agencies have in common is the managerial nature of their tasks and consequently also their lack of hard decision-making powers.⁴⁶ The second type of agencies are the 'pre-decision making ones', characterised by the same lack of decision-making powers as ordinary agencies, however, in contrast to the latter, they influence the Commission significantly in adopting their final decisions. Hence, even though *de jure* they cannot adopt legally binding decisions, in practice their impact on the Commission is so substantial that they are said to enjoy *de facto* decision-making powers.⁴⁷ The third group consists of real 'decision-making agencies', hence agencies that have the power to adopt decisions, which are legally binding on third parties.⁴⁸ The fourth and final category of agencies is composed of 'rulemaking' or regulatory agencies, ie agencies that enjoy broad discretionary powers to 'translate (...) EU guidelines into concrete instruments' of general application. It is mostly argued that those agencies do not exist at EU level.⁴⁹

When it comes to potential conflicts with the *Meroni* doctrine, especially decision-making and regulatory agencies are under consideration. Hence, when talking in terms of different categories of agencies, it is necessary to determine first whether the ECHA, in light of its tasks and powers, can be defined as a decision-making agency, and secondly whether this would be in conformity with the strict non-delegation doctrine. This will be subject of chapters three and four.

⁴⁵ Stefan Griller and Andreas Orator, 'Everything under Control? The "Way Forward" for European Agencies in the Footsteps of the Meroni Doctrine' (2010) 35(1) *European Law Review* 3, 6.

Of course, different classification systems have been developed by different academics. For other categorisations of agencies see for example: Herwig CH Hofmann, 'Agency Design in the European Union' (2010) 28(2) *Windsor Yearbook of Access to Justice* 309; Ellen Vos, 'EU Agencies on the Move: Challenges Ahead' (2016) SIEPS Working Paper (forthcoming).

⁴⁶ Stefan Griller and Andreas Orator, 'Everything under Control? The "Way Forward" for European Agencies in the Footsteps of the Meroni Doctrine' (2010) 35(1) *European Law Review* 3, 6.

⁴⁷ *ibid.*

⁴⁸ *ibid.*

⁴⁹ *ibid.* 7.

1.4. Conclusion

Considering the foregoing it can thus be observed that the EU has resorted to the creation of agencies more frequently over the years.⁵⁰ Although the motives behind this choice of delegating powers to non-majoritarian bodies vary from the need for crisis reaction measures to the depolitisation of EU decision-making or the need for more cooperation with national regulatory authorities,⁵¹ the three waves of agency creation revealed a general trend of delegating an increasing scope of powers to EU agencies.⁵² This continuous evolution of the agency construct is probably one of the reasons for the lack of an official definition or at least characterization of ‘agencies’. Still, as has been shown by both the Commission as well as academics such as Griller and Orator, by means of deduction some common features of agencies can be established.⁵³ Moreover, it is possible to group them according to the scope of their prerogatives.⁵⁴

Before turning to the analysis of ECHA’s powers in chapter three and characterizing it as either an ordinary, pre-decision-making, decision-making, or regulatory agency respectively, the following chapter will go into detail about the limits governing the delegation of powers to agencies at EU level. In that regard, the cases of *Meroni*⁵⁵ and *ESMA Short-selling*⁵⁶ will be analysed. This will be done with a view to examining later on whether the ECHA, as an EU agency and with its broad range of powers, complies with those requirements or whether they go beyond the limited scope established by the CJEU.⁵⁷

⁵⁰ See section 1.1.

⁵¹ *ibid.*

⁵² See section 1.2.

⁵³ See section 1.3.

⁵⁴ See section 1.2.

⁵⁵ Case 9/56 *Meroni & Co, Industrie Matallurgische S.P.A. v. High Authority* [1957–1958] ECLI:EU:C:1958:7.

⁵⁶ Case C-270/12 *the United Kingdom v. Council and European Parliament* [2014] ECLI:EU:C:2014:18.

⁵⁷ For the sake of simplicity, throughout the Thesis the abbreviation CJEU will be used, although it would technically only be correct to talk about the Court of Justice of the European Coal and Steel Community for the period between 1952 and 1958 and the Court of Justice of the European Communities for the period from 1958 to 2009.

See for example: Publications Office, ‘The Court of Justice of the European Communities: Historic Landmarks, Buildings and Symbols’ (2007) <https://www.google.be/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&cad=rja&uact=8&ved=0ahUKEwia3rGm3tHVAhWG2hoKHWJuBGUQFggwMAE&url=http%3A%2F%2Fcuria.europa.eu%2Fjcms%2Fjcms%2FP_90443%2F&usq=AFQjCNGzSg9jKJbZPqqwzm3LWETffhsPMQ> last accessed 24 August 2017; Ditlev Tamm, ‘The History of the Court of Justice of the European Union Since its Origin’ in Court of Justice of the European Union (ed), *The Court of Justice and the Construction of Europe: Analyses and Perspectives on Sixty Years of Case Law* (Asser Press 2013).

Chapter 2: Delegation of powers to agencies

This chapter deals with the delegation of powers to agencies and the associated limits established by the CJEU in its case law. To that end, the concept of ‘delegation’ will be shortly addressed in section 2.1. in order to establish whether it is reasonable to characterise the empowerment of agencies as ‘delegation’ to begin with and consequently also whether the boundaries established by the Court need to be observed when creating and warranting agencies at EU level. In the subsequent sections the just mentioned limits as well as their significance will be further elaborated on.

2.1. Delegation of powers

It is often taken for granted that the empowerment of agencies can be qualified as a delegation and that therefore, in the same vein, agencies need to comply with a number of delegation limits established by the CJEU. However, this analogy should not simply be drawn without looking at the details of the delegation concept. Unfortunately, a uniform understanding of ‘delegation’ does not exist.⁵⁸ On the contrary, various academics have defined the concept differently, as already illustrated by Chamon.⁵⁹ It would go beyond the scope of this Thesis to go into all of these concepts in detail. Suffice it to say that when looking at different definitions, it becomes obvious that the transfer of powers to agencies cannot be qualified as a delegation in a traditional sense.⁶⁰ At first glance, especially two problems can be identified, namely the lack of an explicit norm authorising a delegation of powers to agencies⁶¹ as well as the premise that a delegator can only delegate the powers it possesses itself.⁶² With regard to the former, it can be argued that it is true that there is no explicit provision in the Treaties allowing powers to be delegated to agencies of the EU. In other words, contrary to the circumstances in *Meroni*, the Treaties do not give the Commission a

⁵⁸ Merijn Chamon, *EU Agencies: Legal and Political Limits to the Transformation of the EU Administration* (PDF version Chapter 4, Oxford University Press 2016), 114-123.

⁵⁹ *ibid.*

⁶⁰ *ibid.* 121.

⁶¹ Edoardo Chiti, ‘An Important Part of the EU’s Institutional Machinery: Features, Problems and Perspectives of European Agencies’ (2009) 46(5) *Common Market Law Review* 1395, 1422-1423; Merijn Chamon, *EU Agencies: Legal and Political Limits to the Transformation of the EU Administration* (PDF version Chapter 4, Oxford University Press 2016), 117.

⁶² Edoardo Chiti, ‘An Important Part of the EU’s Institutional Machinery: Features, Problems and Perspectives of European Agencies’ (2009) 46(5) *Common Market Law Review* 1395, 1422-1423; Miroslava Scholten and Marloes van Rijsbergen, ‘The ESMA-Short Selling Case: Erecting a New Delegation Doctrine in the EU upon the *Meroni-Romano* Remnants’ (2014) 41(4) *Legal Issues of Economic Integration* 389, 402.

specific power and neither do they provide for the delegation of those powers to independent bodies, such as agencies.⁶³ However, just because the specific situation of delegating powers to agencies is not explicitly provided for in the Treaties, does not mean that it was not intended to be included implicitly. Indeed, the Court held in *ESMA Short-selling* that the Articles 290 and 291 of the TFEU, dealing with the exercise of delegated and implementing powers, are not exhaustive.⁶⁴ It underlined its reasoning by drawing to the attention of the drafters of the Treaties, who, by way of referring to agencies in provisions such as Articles 263, 265, 267 or 277 TFEU, indicated that they should be allowed to receive certain powers.⁶⁵ With regard to the requirement that a delegating authority can only delegate powers it enjoys, it is often criticized that the powers EU agencies receive cannot easily be identified as EU competences to begin with.⁶⁶ What is meant by this is that EU agencies, instead of only carrying out tasks that were previously performed by the Commission, partly took over tasks that used to be in the hands of national regulatory authorities.⁶⁷ In that regard it is often argued that the *agencification* of the EU executive is characterized by a 'Europeanization of powers' or a conferral of powers from Member States to the European Union rather than a delegation.⁶⁸ Therefore, as a first step, it is legitimate to question the applicability of the *Meroni* doctrine to the *agencification* of the Union administration. However, as recently indicated by the Council Legal Service in its opinion on the SRM, this strict emphasis on the difference between conferrals and delegations should not be decisive for the relevance of the *Meroni* requirements on its own.⁶⁹ In fact, the Court seems to have gone in the same direction by ignoring the extensive elaboration on the difference between conferrals and delegations drawn by the AG in the *ESMA Short-selling* case.⁷⁰

⁶³ Miroslava Scholten and Marloes van Rijsbergen, 'The ESMA-Short Selling Case: Erecting a New Delegation Doctrine in the EU upon the *Meroni-Romano* Remnants' (2014) 41(4) *Legal Issues of Economic Integration* 389, 402.

⁶⁴ C-270/12 *The United Kingdom v. Council and European Parliament* [2014] ECLI:EU:C:2014:18, paras 86-87.

⁶⁵ *ibid* para 80.

⁶⁶ Edoardo Chiti, 'An Important Part of the EU's Institutional Machinery: Features, Problems and Perspectives of European Agencies' (2009) 46(5) *Common Market Law Review* 1395, 1422-1423; Miroslava Scholten and Marloes van Rijsbergen, 'The ESMA-Short Selling Case: Erecting a New Delegation Doctrine in the EU upon the *Meroni-Romano* Remnants' (2014) 41(4) *Legal Issues of Economic Integration* 389, 402; Merijn Chamon, *EU Agencies: Legal and Political Limits to the Transformation of the EU Administration* (PDF version Chapter 4, Oxford University Press 2016), 69ff.

⁶⁷ *ibid*.

⁶⁸ Renaud Dehousse, 'Misfits: EU Law and the Transformation of European Governance' in Christian Joerges and Renaud Dehousse (eds), *Good Governance in Europe's Integrated Market* (Oxford University Press 2002), 221.

⁶⁹ Merijn Chamon, *EU Agencies: Legal and Political Limits to the Transformation of the EU Administration* (PDF version Chapter 4, Oxford University Press 2016), 86-87; Legal Service of the Council of the European Union, Doc. 14547/13.

⁷⁰ C-270/12 *The United Kingdom v. Council and European Parliament* [2014] ECLI:EU:C:2014:18.

of C-270/12 *The United Kingdom v. Council and European Parliament* [2014] ECLI:EU:C:2014:18 (Opinion of AG Jääskinen).

Last but not least, in the same case, the Court confirmed the applicability of the doctrine to the delegation of powers to agencies.⁷¹ In light of the foregoing it is reasonable to assume that even though the empowerment of agencies can certainly not be classified as traditional delegation, this does not rule out the applicability of the limits to delegations of power established by the Court. This assumption can also be supported by the fact that, had agencies not been the designated recipients of those powers at EU level, they would probably have been conferred to the Commission. In other words, the empowerment of agencies constitutes in a sense a *de facto* delegation, bearing in mind that the Commission has been deprived of a potential conferral of powers.⁷²

Having established that it is reasonable to apply the so-called ‘anti-delegation doctrine’ to the delegation of powers to EU agencies, the following sections will go into depth about the cases that provided the basis for this doctrine.

2.2. *Meroni v. High Authority*:⁷³ Limits to the delegation of powers to agencies

The Court’s judgment in *Meroni v. High Authority* is usually referred to as having severely limited the possibility of delegating powers to EU agencies. As demonstrated by cases such as *Romano*⁷⁴, *Alliance for Natural Health*⁷⁵ or *ESMA Short-selling*, even though the *Meroni* case was decided already in 1958 under the old ECSC regime, it remains valid and continues to form the main point of reference when it comes the scope of agencies’ powers.⁷⁶

In the *Meroni* case, the Italian steel company *Meroni* was required to pay a sum of money to the Imported Ferrous Scrap Equalization Fund. The applicant, among others,

⁷¹ C-270/12 *The United Kingdom v. Council and European Parliament* [2014] ECLI:EU:C:2014:18, paras 41-55.

⁷² Miroslava Scholten and Marloes van Rijsbergen, ‘The ESMA-Short Selling Case: Erecting a New Delegation Doctrine in the EU upon the *Meroni-Romano* Remnants’ (2014) 41(4) *Legal Issues of Economic Integration* 389, 404.

⁷³ In existing literature there are divergent opinions on what elements the *Meroni* doctrine includes. The present description of the case thus joins the ranks of a group of different interpretations of the judgment. For other interpretations see for example the overview provided in: Merijn Chamon, *EU Agencies: Legal and Political Limits to the Transformation of the EU Administration* (PDF version Chapter 4, Oxford University Press 2016), 80-83.

⁷⁴ Case 98/80, *Giuseppe Romano v. Institut national d’assurance maladie-invalidité* [1981] ECLI:EU:C:1981:104.

⁷⁵ Joined Cases C-154/04 and C-155/04 *Alliance for Natural Health and Others* [2005] ECLI:EU:C:2005:449.

⁷⁶ Joined Cases C-154/04 and C-155/04 *Alliance for Natural Health and Others* [2005] ECLI:EU:C:2005:449, para 90; C-270/12 *The United Kingdom v. Council and European Parliament* [2014] ECLI:EU:C:2014:18, paras 41-55; Ellen Vos, ‘EU Agencies on the Move: Challenges Ahead’ (2016) SIEPS Working Paper, 17-18 (forthcoming).

challenged the delegation of powers of financial operation to the so-called Brussels Agencies, private bodies founded under Belgian law and empowered by Article 53(1)(a) of the ECSC Treaty.⁷⁷ The CJEU, in its judgment, laid down conditions restricting the scope of powers that can legally be transferred to agencies, which are nowadays generally referred to as constituting the ‘anti-delegation doctrine’⁷⁸ or ‘*Meroni* doctrine’.⁷⁹ The different aspects of this doctrine will be discussed below.

To begin with, notwithstanding the absence of an explicit reference to the practice of delegating powers in the ECSC Treaty,⁸⁰ the Court confirmed the legality of the latter where it would be necessary to ensure the effective execution of the Treaties.⁸¹ However, in turn it went on to qualify this permission by laying down specific conditions a delegation of powers to agencies needs to fulfil in order to be eventually approved.

First of all, the Court limited the delegation of powers as such by requiring that the delegating authority be restricted by the scope of its own powers, which means that it can only delegate the powers it possesses itself.⁸² In the same vein, in exercising their tasks, agencies are subject to the same conditions that would have circumscribed the High Authority in accomplishing those tasks.⁸³ Secondly, the Court limited the scope of powers to be delegated by constraining them to ‘clearly defined executive powers’.⁸⁴ Indeed, in *Meroni*, the contested decision was held to be unlawful, because it transferred ‘true discretionary powers’ to the Belgian agencies.⁸⁵ Finally, the Court recognised the importance of strict control by the delegating authority of the powers

⁷⁷ Case 9/56 *Meroni & Co, Industrie Metallurgische S.P.A. v. High Authority* [1957–1958] ECLI:EU:C:1958:7.

⁷⁸ It is sometimes also called the ‘limited delegation doctrine’ or the ‘non-delegation’ doctrine.

⁷⁹ Merijn Chamon, ‘EU Agencies between *Meroni* and *Romano* or the Devil and the Deep Blue Sea’ (2011) 48(4) *Common Market Law Review* 1055, 1057; Ellen Vos, ‘European Agencies and the Composite EU Executive’ in Michelle Everson, Cosimo Monda and Ellen Vos (eds), *European Agencies in between Institutions and Member States* (Kluwer Law International 2014), 40.

⁸⁰ Stefan Griller and Andreas Orator, ‘Everything under Control? The “Way Forward” for European Agencies in the Footsteps of the *Meroni* Doctrine’ (2010) 35(1) *European Law Review* 3, 7.

⁸¹ Case 9/56 *Meroni & Co, Industrie Metallurgische S.P.A. v. High Authority* [1957–1958] ECLI:EU:C:1958:7, 151-152.

⁸² Case 9/56 *Meroni & Co, Industrie Metallurgische S.P.A. v. High Authority* [1957–1958] ECLI:EU:C:1958:7, 150; Pieter Van Cleynenbreugel, ‘*Meroni* Circumvented? Article 114 TFEU and EU Regulatory Agencies’ (2014) 21(1) *Maastricht Journal of European and Comparative Law* 64, 79-80.

⁸³ *ibid.*

⁸⁴ *ibid.*

⁸⁵ Case 9/56 *Meroni & Co, Industrie Metallurgische S.P.A. v. High Authority* [1957–1958] ECLI:EU:C:1958:7, 152.

delegated on the basis of objective criteria. Only in case of clearly defined executive powers would such a review be strict enough.⁸⁶

In essence, the underlying rationale for the Court's restrictive stance towards the delegation of powers to agencies can be found in the preservation of the institutional balance within the European Union, which is perceived to be a fundamental principle of Union law.⁸⁷ The CJEU argued that this balance would only be upheld where clearly defined executive powers were delegated, but would be upset in case of a delegation of discretionary powers, because the latter practice would amount to an 'actual transfer of responsibility'.⁸⁸

As can be witnessed from the above reasoning, the Court was rather unclear in laying down the limits to a delegation of powers to agencies. It missed the opportunity to go into detail about what it is that makes powers discretionary in nature and what precisely characterizes a clearly defined executive power. Instead, it only provided some general statements that may or may not be interpreted as constituting the outer edges of what is allowed. Indeed, it seems that in the Court's view, the exercise of discretionary powers requires agencies to make 'difficult choices' by taking into account both economic factors and the circumstances surrounding the execution.⁸⁹ The realization of 'actual economic policy' is thus not allowed.⁹⁰ Moreover, it is put forward that discretion in the hands of a body means that the latter's choices would replace the choices of the delegator and therefore lead to an 'actual transfer of responsibility'.⁹¹ On the other hand, clearly defined executive powers are characterized by the fact that their delegation does not alter the institutional balance of powers within the European Union and neither does it affect 'the consequences involved in the powers concerned'.⁹² However, those indications do not make it possible to clearly apply the *Meroni* doctrine in practice. They only deliver a starting point that can be applied differently on a case-by-case basis but do in no way eliminate the difficulties

⁸⁶ *ibid.*

⁸⁷ Case 9/56 *Meroni & Co, Industrie Metallurgische S.P.A. v. High Authority* [1957–1958] ECLI:EU:C:1958:7, 152; Merijn Chamón, 'EU Agencies: Does the Meroni Doctrine Make Sense?' (2010) 17(1) *Maastricht Journal of European and Comparative Law* 281, 289.

⁸⁸ Case 9/56 *Meroni & Co, Industrie Metallurgische S.P.A. v. High Authority* [1957–1958] ECLI:EU:C:1958:7, 152.

⁸⁹ *ibid.*

⁹⁰ *ibid.*

⁹¹ *ibid.*

⁹² *ibid.*

related to the application of the *Meroni* test to agencies of the European Union and their powers. Indeed, the room for manoeuvre those guidelines allow for becomes apparent in the diverging interpretations used by different scholars,⁹³ which is just another demonstration of the problems related to the application of the *Meroni* requirements.

2.3. The *ESMA Short-selling Case*

The issue of delegation of powers to agencies recently appeared anew before the CJEU in the so-called *ESMA Short-selling case*, though this time in a different context, as the agency at issue was an EU one. The body entrusted with exercising the delegated tasks was the European Securities and Markets Authority (hereinafter ESMA), which is one of the three agencies of the European Supervisory System created in reaction to the financial crisis of 2008.⁹⁴ Just as the ECHA, the ESMA is mostly qualified as a particular strong agency and has attracted a lot of attention due to its broad range of powers, including not only supervisory, but also decision-making ones.⁹⁵ In light of the clearly established delegation limits in *Meroni* it was therefore not very surprising that Member States sought to challenge the legality of this delegation of powers. Thus, by its action for annulment brought in 2012, the United Kingdom challenged the legality of Article 28 of the Short Selling Regulation.⁹⁶ The latter provided that ESMA was allowed take legally binding decisions in case there was a 'threat to the orderly functioning and integrity of financial markets or to the stability of the whole or part of the financial system in the Union'.⁹⁷

The UK challenged this delegation of powers on three different grounds. First of all, they challenged the compatibility of the delegation of powers with Articles 290 and 291 TFEU, neither of which mention agencies as being entitled to receive implementing or

⁹³ For a good summary of different interpretations of the *Meroni* conditions see: Merijn Chamon, *EU Agencies: Legal and Political Limits to the Transformation of the EU Administration* (PDF version Chapter 4, Oxford University Press 2016), 80-83.

⁹⁴ Miroslava Scholten and Marloes van Rijsbergen, 'The ESMA-Short Selling Case: Erecting a New Delegation Doctrine in the EU upon the *Meroni-Romano* Remnants' (2014) 41(4) *Legal Issues of Economic Integration* 389, 391-392.

⁹⁵ *ibid.*

⁹⁶ Case C-270/12 *The United Kingdom v. Council and European Parliament* [2014] ECLI:EU:C:2014:18, para 26.

⁹⁷ Regulation (EU) 236/2012 on Short Selling and certain Aspects of Credit Default Swaps [2012] OJ L 86/3, Art. 28 (hereinafter Short Selling Regulation).

delegating powers respectively.⁹⁸ Moreover, they disputed the appropriateness of Article 114 TFEU as legal basis for the establishment of an agency, such as the ESMA.⁹⁹ Finally, and most importantly in the context of this Thesis, the UK argued that the delegation of powers to ESMA would amount to a breach of both the *Meroni* doctrine and the *Romano* ruling.¹⁰⁰ This last complaint will be the focus of the following paragraphs.

Next to opening up the framework for delegating powers established under Articles 290 and 291 of the TFEU,¹⁰¹ approving Article 114 TFEU as legal basis,¹⁰² and confirming that, by means of reference to provisions such as Article 263 or 277 TFEU, agencies can take acts of general application that are challengeable before Court,¹⁰³ the CJEU also rejected the argument pointing at the incompatibility of ESMA's powers with the *Meroni* doctrine and thereby dismissed the action of the United Kingdom in its entirety.¹⁰⁴ Indeed, the analysis of the compatibility of the short selling provision with the *Meroni* case is the most crucial part of the ruling. Considering the fact that the *Meroni* case dates back to 1958 and taking into account the overall change of context that has occurred over time, the Court surprisingly upheld the *Meroni* doctrine. However, in its elaboration about the alleged requirements of the 'non-delegation doctrine', it seems to have implicitly broadened the possibility for delegating powers to EU agencies.¹⁰⁵ In doing so, the Court specifically emphasised that instead of concerning independent bodies established under private law, the entity in question in the *Short-selling* case was an official EU body.¹⁰⁶ With regard to the permissible scope of delegated powers the CJEU stated that the latter need to be 'circumscribed by various conditions and criteria', ie precisely delineated, and therefore 'amenable to judicial review'.¹⁰⁷ It therefore found itself justified to conclude that in the absence of 'a

⁹⁸ Case C-270/12 *The United Kingdom v. Council and European Parliament* [2014] ECLI:EU:C:2014:18, paras 69-76.

⁹⁹ *ibid* paras 88-96.

¹⁰⁰ *ibid* paras 27-40 and 56-62.

¹⁰¹ *ibid* paras 86-87.

¹⁰² *ibid* paras 117-118.

¹⁰³ *ibid* paras 63-68.

¹⁰⁴ *ibid* paras 54-55, 67-68 and 119.

¹⁰⁵ *ibid* paras 41-42.

¹⁰⁶ *ibid* para 43.

¹⁰⁷ *ibid* paras 45 and 53.

very large measure of discretion' in the hands of the ESMA, the delegation of powers was compatible with the framework of limitation established in *Meroni*.¹⁰⁸

When it comes to determining the exact meaning of the *ESMA* judgment for the delegation of powers to agencies, opinions tend to slightly differ. The potential added value of the *ESMA* case will therefore be subject of the next subsection.

2.4. A gradual drift away from the strict *Meroni* requirements?

As the *Meroni* doctrine continues to constitute good law, one might wonder whether the *ESMA* ruling has indeed opened the way for a more flexible approach towards the delegation of powers to outside bodies. In that regard, the significance of different aspects of the case is often highlighted. First of all, some scholars interpret the ruling in *ESMA* as underlining the importance of control mechanisms with regard to the powers delegated. They think that what the Court is saying in essence is that the existence of sufficient control mechanisms will remedy for the delegation of discretionary powers to EU agencies.¹⁰⁹ Other authors praise the judgment for adapting the *Meroni* doctrine to the present needs and state of affairs.¹¹⁰ Under this heading it is first of all put forward that the Court realized the pressing necessity to strike a balance between the need to uphold the 'constitutional non-delegation principle' and the Union objective of establishing an internal market.¹¹¹ Moreover, scholars agree on the accuracy of the Court's reference to the different nature of the *Meroni* agencies and the *ESMA*. Whereas the former were national private law bodies, the *ESMA* is an EU public law agency that has received its powers directly from the

¹⁰⁸ *ibid* para 54.

¹⁰⁹ Phedon Nicolaides and Nadir Preziosi, 'Discretion and Accountability: The *ESMA* Judgment and the *Meroni* Doctrine' (2014) *Bruges European Economic Research Papers* 30/2014, 21 <<http://aei.pitt.edu/57214/>> last accessed 24 August 2017; Gianni Lo Schiavo, 'A Judicial Re-Thinking on the Delegation of Powers to European Agencies under EU Law? Comment on Case C-270/12 *UK v. Council and Parliament*' (2015) 16(2) *German Law Journal* 315, 324-325.

¹¹⁰ see for example: Merijn Chamon, 'EU Agencies between *Meroni* and *Romano* or the Devil and the Deep Blue Sea' (2011) 48(4) *Common Market Law Review* 1055, 1072-1074; Jacques Pelkmans and Marta Simoncini, 'Mellowing *Meroni*: How *ESMA* Can Help Build the Single Market' (CEPS Commentary Thinking Ahead of Europe 2014), 5-6 <www.ceps.eu/publications/mellowing-meroni-how-esma-can-help-build-single-market> last accessed 24 August 2017; Gianni Lo Schiavo, 'A Judicial Re-Thinking on the Delegation of Powers to European Agencies under EU Law? Comment on Case C-270/12 *UK v Council and Parliament*' (2015) 16(2) *German Law Journal* 315, 324; Ellen Vos, 'EU Agencies on the Move: Challenges Ahead' (2016) SIEPS Working Paper, 20 (forthcoming).

¹¹¹ Art. 3(3) TFEU; Jacques Pelkmans and Marta Simoncini, 'Mellowing *Meroni*: How *ESMA* Can Help Build the Single Market' (CEPS Commentary Thinking Ahead of Europe 2014) <www.ceps.eu/publications/mellowing-meroni-how-esma-can-help-build-single-market> last accessed 24 August 2017, 5.

EU legislator.¹¹² To the extent that the *ESMA* case is interpreted as aligning the *Meroni* requirements to the present-day context, the judgment is even referred to as ‘*Meroni 2.0*’.¹¹³

However, ultimately, even though a more flexible approach towards the delegation of powers to agencies seems to be emerging, the *Meroni* case has not yet been overruled. Furthermore, one significant shortcoming of the *ESMA Short-selling* case is the Court’s ignorance of cases such as for example *Schröder*¹¹⁴ or *Rütgers*¹¹⁵ in concluding that ESMA does not possess ‘a very large measure of discretion’ in exercising its powers.¹¹⁶ Indeed, in those cases the Court explicitly confirmed that EU agencies have to carry out wide discretionary tasks.¹¹⁷ In *Schröder* the Court recognised the limited scope of judicial review when it comes to decision-making agencies such as the CVPO, simply because they enjoy a broad discretion in the exercise of their power¹¹⁸ whereas in the latter case, which concerned the ECHA, it even held that the Agency has ‘a broad discretion in a sphere which entails political, economic and social choices on its part, and in which it is called upon to undertake complex assessments’.¹¹⁹ These judgments will come back later on when discussing ECHA’s powers and their compliance with *Meroni* in greater detail.

2.4. Conclusion

It can be concluded that in spite of the lack of a uniform definition of what constitutes a delegation, the empowerment of agencies can at least be described as a *de facto* delegation.¹²⁰ It is therefore reasonable to apply the delegation limits established by

¹¹² Merijn Chamon, ‘EU Agencies between *Meroni* and *Romano* or the Devil and the Deep Blue Sea’ (2011) 48(4) *Common Market Law Review* 1055, 1059; Gianni Lo Schiavo, ‘A Judicial Re-Thinking on the Delegation of Powers to European Agencies under EU Law? Comment on Case C-270/12 *UK v Council and Parliament*’ (2015) 16(2) *German Law Journal* 315, 324-325; Ellen Vos, ‘EU Agencies on the Move: Challenges Ahead’ (2016) SIEPS Working Paper, 20-21 (forthcoming).

¹¹³ Ellen Vos, ‘EU Agencies on the Move: Challenges Ahead’ (2016) SIEPS Working Paper, 20 (forthcoming).

¹¹⁴ Case T-187/06 *Schröder v CPVO* [2008] ECLI:EU:T:2008:511.

¹¹⁵ Case T-96/10 *Rütgers Germany GmbH v. ECHA* [2013] ECLI:EU:T:2013:109.

¹¹⁶ Case C-270/12 *The United Kingdom v. Council and European Parliament* [2014] ECLI:EU:C:2014:18, para 54.

¹¹⁷ Herwig CH Hofmann, ‘Agency Design in the European Union’ (2010) 28(2) *Windsor Yearbook of Access to Justice* 309, 318; Merijn Chamon, ‘EU Agencies between *Meroni* and *Romano* or the Devil and the Deep Blue Sea’ (2011) 48(4) *Common Market Law Review* 1055, 1059; Ellen Vos, ‘EU Agencies on the Move: Challenges Ahead’ (2016) SIEPS Working Paper, 21-22 (forthcoming).

¹¹⁸ Case T-187/06 *Schröder v CPVO* [2008] ECLI:EU:T:2008:511, para 59.

¹¹⁹ Case T-96/10 *Rütgers Germany GmbH v. ECHA* [2013] ECLI:EU:T:2013:109, para 134.

¹²⁰ Miroslava Scholten and Marloes van Rijsbergen, ‘The *ESMA-Short Selling* Case: Erecting a New Delegation Doctrine in the EU upon the *Meroni-Romano* Remnants’ (2014) 41(4) *Legal Issues of Economic Integration* 389, 404.

the CJEU in its case law to the *agencification* process in the European Union. Those limits are often subsumed under the heading ‘anti-’ or recently ‘limited delegation doctrine, that found its origin in the *Meroni* case.¹²¹ The most problematic condition laid down in the former is the need for the powers delegated to be ‘clearly described executive’ ones, to the detriment of powers that are discretionary in nature.¹²² It is still not clear what exactly characterises such powers. Indeed, this aspect of the judgment seems to be the one that the Court also focussed on in the *ESMA Short-selling* case. Instead of only confirming the legitimacy of the *Meroni* requirements, it slightly modified it by allowing some degree of discretion to be given to agencies.¹²³ However, as the Court did not formally overrule the *Meroni* requirements and they consequently continue to constitute good law, it is necessary to test ECHA’s powers against both the *Meroni* conditions as well as the *ESMA* judgment. In order to be able to develop a well-reasoned analysis, ECHA’s structure and tasks in the overall system of the EU’s chemicals policy will be examined in turn.

¹²¹ Ellen Vos, ‘EU Agencies on the Move: Challenges Ahead’ (2016) SIEPS Working Paper, 16 (forthcoming).

¹²² Case 9/56 *Meroni & Co, Industrie Matallurgische S.P.A. v. High Authority* [1957–1958] ECLI:EU:C:1958:7, 152.

¹²³ Case C-270/12 *The United Kingdom v. Council and European Parliament* [2014] ECLI:EU:C:2014:18, paras 41-42.

Chapter 3: Delegation of powers to the European Chemicals Agency

The European Chemicals Agency was established along with the adoption of the REACH Regulation (Registration, Evaluation, Authorization and Restriction of Chemicals) in 2007 as part of the new framework for chemicals in the European Union and is charged with very important powers when it comes to implementing the Union legislation concerning chemicals.¹²⁴ As has been established in section 1.2. a uniform concept of 'agencies' is still missing in the European Union. However, drawing on the definition developed by Griller and Orator, it will become apparent in the forthcoming that the ECHA can indeed be characterised as an EU agency. Next to that it has also been concluded in section 2.1. that it is at least not unreasonable to qualify the empowerment of agencies as a delegation. ECHA does not constitute an exception in that regard.

ECHA's qualification as an agency that is the recipient of delegated powers triggers the need for it to comply with the requirements concerning the delegation of powers to agencies as established in *Meroni* and *ESMA Short-selling*. In light of the foregoing, with a view to establishing the exact nature of the ECHA in this chapter and analysing the compatibility of ECHA's powers with the non-delegation doctrine subsequently in chapter four, the present chapter deals with the organisation and the functioning of the European Chemicals Agency and most importantly its areas of involvement as well as its powers. To this end, section 3.1. provides the reader first with some information about the context surrounding the establishment of the ECHA in 2007 and about chemicals policy in the EU. In that regard the four Regulations requiring ECHA involvement will be shortly explained. Next, section 3.2. tackles ECHA's internal organization. In section 3.3. the scope of ECHA's powers under the different chemical regulations is analysed. Finally, the chapter is completed by drawing a conclusion about the scope of ECHA's powers and by regimenting the Agency into the categorisation established earlier on (see section 1.3.).

¹²⁴ REACH Regulation, Art. 75.

3.1. The EU's approach to chemicals

The establishment of the European Chemicals Agency resulted out of a major reform of the chemicals policy in the EU, which had been in the making since 1998, and was eventually finalised in 2007 with the adoption of Regulation 1907/2006 on the Registration, Evaluation and Authorisation of Chemicals (REACH Regulation).¹²⁵ This overhaul of the Union's chemicals policy was the consequence of a general dissatisfaction with the web of directives and regulations dealing with chemicals control that were in existence before 2007.¹²⁶ In essence, this was the case, because the former regime was felt to be characterized by a lack of sufficient knowledge about chemicals and thereby failed to provide satisfactory protection against the potential harmful effects of those substances for both humans as well as the environment.¹²⁷ The pre-2007 policy functioning was based on two important distinctions, namely between dangerous and other substances as well as, most importantly, between new substances and old ones.¹²⁸ The latter were defined as chemicals put onto the market before 1981 and did not have to conform to requirements as strict as the new chemicals.¹²⁹ More precisely, whereas the placing on the market of chemicals after 1981 was conditioned upon extensive information, notification and testing requirements, existing chemicals escaped those requirements except for rare cases where severe risks had been discovered.¹³⁰ As existing substances made up almost 99% of the chemicals in circulation, the consequences of this difference in treatment

¹²⁵ REACH Regulation, Art. 75; Steven Vaughan, *EU Chemicals Regulation: New Governance, Hybridity and REACH* (Edward Elgar Publishing 2015), 28-29.

¹²⁶ Commission (EC), 'White Paper on the Strategy for a Future Chemicals Policy' (White Paper) COM (2001) 88 final, 4-5.

Chemicals policy was previously mostly governed by the following directives and regulations: Council Directive (EEC) 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances [1967] OJ L 196/1; Council Directive (EEC) 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations [1976] OJ L 262/201; Council Regulation (EEC) 793/93 on the evaluation and control of existing chemical substances [1993] OJ L 084/1; Council Directive (EC) 1999/45 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations [1999] OJ L 200/1.

¹²⁷ Commission (EC), 'White Paper on the Strategy for a Future Chemicals Policy' (White Paper) COM (2001) 88 final, 4-5.

¹²⁸ Steven Vaughan, *EU Chemicals Regulation: New Governance, Hybridity and REACH* (Edward Elgar Publishing 2015), 28-29.

¹²⁹ Ineke Gubbels-van Hal and Jacques Pelkmans, 'Is REACH going well?' (2009) CEPS Policy Brief 198/2009, 2 <www.ceps.eu/publications/reach-going-well> last accessed 24 August 2017; Christian Hey, Klaus Jacob and Axel Volkery, 'Better Regulation by new Governance Hybrids? Governance Models and the Reform of European Chemicals Policy' (2007) 15(18) *Journal of Cleaner Production* 1859, 1863.

¹³⁰ Christian Hey, Klaus Jacob and Axel Volkery, 'Better Regulation by new Governance Hybrids? Governance Models and the Reform of European Chemicals Policy' (2007) 15(18) *Journal of Cleaner Production* 1859, 1863-64.

were very serious.¹³¹ Next to this, the ineffectiveness of the old chemicals policy can also be traced back to the fact that national regulatory authorities were the main actors, as they had to perform completeness checks, risk assessments and needed to notify their findings to the Commission. In other words, there was no direct contact between on the one hand, the industry and on the other hand, the Commission, which resulted in high costs and immense delays.¹³²

In order to prevent the internal market from being further distorted and human health and environment from being damaged, it was decided that a new more strict and precise regime should be adopted: the REACH.¹³³ To this end, already in 2001, 3 years after the Commission first pointed to the need to revise chemicals policy at a debate of the Council of Environment Ministers in Chester, it published a White Paper on the 'Strategy for a future Chemicals Policy' circumscribing what the new chemicals policy should look like in order to address the previous shortcomings.¹³⁴ However, due to the sensitive nature of the matters at stake, the negotiation processes leading to the adoption of the REACH Regulation took tremendously long, so that it only entered into force six years later. In the following, the REACH Regulation will be further thematised.

3.1.1. Regulation 1907/2006: Registration, Evaluation, Authorisation and Restriction of Chemicals

All in all, when comparing it with the old regime, the new regulatory framework for chemicals is characterized mainly by three innovations, namely the abolishment of the distinction between existing substances and new substances,¹³⁵ the replacement of national regulatory authorities as main actors,¹³⁶ as well as the creation of the European Chemicals Agency, that is supposed to operate independently.¹³⁷ First of all,

¹³¹ *ibid.*

¹³² Veerle Heyvaert, 'The EU Chemicals Policy: Towards Inclusive Governance?' (2008) Society and Economy Working Papers 7/2008, 3-4 <<http://eprints.lse.ac.uk/23562/>> last accessed 24 August 2017.

¹³³ Ineke Gubbels-van Hal and Jacques Pelkmans, 'Is REACH going well?' (2009) CEPS Policy Brief 198/2009, 2 <www.ceps.eu/publications/reach-going-well> last accessed 24 August 2017.

¹³⁴ Commission, 'White Paper on the Strategy for a Future Chemicals Policy' COM (2001) 88 final; Steven Vaughan, *EU Chemicals Regulation: New Governance, Hybridity and REACH* (Edward Elgar Publishing), 29.

¹³⁵ Björn Rögnvaldsson Þór and Konstantinos G Margaritis, 'European Chemicals Agency and Good Governance' (2012) Human Rights and Human Welfare Working Papers 69/2012, 10 <<http://www.du.edu/korbel/hrhw/workingpapers/2012/69-rognvaldsson-2012.pdf>> last accessed 24 August 2017.

¹³⁶ *ibid.*

¹³⁷ Björn Rögnvaldsson Þór and Konstantinos G Margaritis, 'European Chemicals Agency and Good Governance' (2012) Human Rights and Human Welfare Working Papers 69/2012, 10-11 <<http://www.du.edu/korbel/hrhw/workingpapers/2012/69-rognvaldsson-2012.pdf>> last accessed 24 August 2017;

as becomes immediately clear from Article 2 of the REACH Regulation, a uniform regime has been established for all substances and chemicals, in that they are covered by the Regulation unless specifically excluded.¹³⁸ Next, in line with its slogan ‘no data, no market’, the industry, ie the private sector, is charged with assessing the risks of and providing information about chemicals.¹³⁹ Those findings, instead of being directly transmitted to the Commission, need to be registered with the ECHA. Only registered substances are allowed to circulate freely on the market and those that are considered to be potentially dangerous may either be authorised for a limited amount of time, be prohibited from operating in the internal market or be banned completely, which is why the role assumed by ECHA is of great importance.¹⁴⁰

More specifically, with regard to the process substances need to go through in order to be accessible on the internal market, three main stages need to be distinguished in the REACH Regulation: registration, evaluation and authorisation.¹⁴¹ In essence, chemical producers and importers that exceed the benchmark laid down in Article 6(1) of the REACH Regulation, namely 1 metric ton of a chemical per year, are obliged to register their product. Registration is effectuated by the submission of a technical explanatory dossier to the European Chemicals Agency.¹⁴² The required information generally increases with the volume of chemicals produced or imported respectively.¹⁴³ Upon reception of the technical dossier, the ECHA will perform a completeness check, which is generally characterized as being automated as well as superficial, and will

Steven Vaughan, *EU Chemicals Regulation: New Governance, Hybridity and REACH* (Edward Elgar Publishing 2015), 64ff.

¹³⁸ Björn Rögnvaldsson Þór and Konstantinos G Margaritis, ‘European Chemicals Agency and Good Governance’ (2012) Human Rights and Human Welfare Working Papers 69/2012, 10 <<http://www.du.edu/korbel/hrhw/workingpapers/2012/69-rognvaldsson-2012.pdf>> last accessed 24 August 2017.

¹³⁹ Christian Hey, Klaus Jacob and Axel Volkery, ‘Better Regulation by new Governance Hybrids? Governance Models and the Reform of European Chemicals Policy’ (2007) 15(18) *Journal of Cleaner Production* 1859, 1864.

¹⁴⁰ Christian Hey, Klaus Jacob and Axel Volkery, ‘Better Regulation by new Governance Hybrids? Governance Models and the Reform of European Chemicals Policy’ (2007) 15(18) *Journal of Cleaner Production* 1859, 1863-64; Steven Vaughan, *EU Chemicals Regulation: New Governance, Hybridity and REACH* (Edward Elgar Publishing), 17.

¹⁴¹ For literature containing a good description of the different stages of REACH see for example: Tanja Ehnert, ‘The European Chemicals Agency: Beyond the Scope of the *Meroni* Doctrine?’ (Master Thesis, Maastricht University 2008), 40-48 <www.stepto.com/attachment.html/3928/20090517164034_thesis-T.Ehnert-withcoverpage%5B1%5D.pdf> accessed 24 August 2017; Marco Bronckers and Yves Van Gerven, ‘Legal Remedies under the EC’s New Chemicals Legislation REACH: Testing a New Model of European Governance’ (2009) 46(6) *Common Market Law Review* 1823, 1829-1836; Jerry H. Yen, ‘Chemical Regulation in the European Union (EU): Registration, Evaluation, and Authorization of Chemicals’ (Congressional Research Service Report 2013), 1-4 <<https://fas.org/sgp/crs/row/RS22673.pdf>> last accessed 24 August 2017; Emilia Korkea-aho, *Adjudicating New Governance: Deliberative Democracy in the European Union* (Routledge 2015), 117-124; Steven Vaughan, *EU Chemicals Regulation: New Governance, Hybridity and REACH* (Edward Elgar Publishing), 51 – 63.

¹⁴² REACH Regulation, Art. 10.

¹⁴³ *ibid* Art. 12.

only be performed more intrusively in form of an actual compliance check for 'at least 5% of registrations in each tonnage category'.¹⁴⁴ Only if the outcome of the completeness check is satisfactory, or the applicant submits the missing information after a lack of data has been communicated to him, the substance will be registered.¹⁴⁵

At the evaluation stage, a distinction needs to be made between dossier evaluation in the first and substance evaluation in the second place. Dossier evaluation is composed of on the one hand the abovementioned compliance check,¹⁴⁶ the resulting decisions of which are either adopted by the Agency or the Commission.¹⁴⁷ The same holds true for the examination of testing proposals submitted by applicants, which form the second part of the dossier evaluation process.¹⁴⁸ The rationale behind this is that the REACH was established on the basis of the aim to avoid animal testing as far as possible. In order to ensure that this principle is adhered to, where applicants fail to comply with the prescribed information requirements, ECHA examines the testing proposals in order to make sure that the use of alternative methods or the sharing of data would not be of any help in the specific case.¹⁴⁹ Afterwards, the so-called substance evaluation process is pulled off through the development by ECHA, in cooperation with the Member States, of criteria allowing for a prioritisation of substances for evaluation on the basis of their potential risk to human health and the environment. By means of those criteria the ECHA can lay down a draft list of substances to be evaluated, called the Community Rolling Action Plan.¹⁵⁰ The burden of evaluating these substances is distributed between different Member States.¹⁵¹ After having done so, the NCAs need to send their draft decision concerning the substance back to the ECHA.¹⁵²

Lastly, when it comes to the final stage of authorization, the underlying rule is that, generally speaking, SVHC, ie substances included in Annex XIV, cannot be put on the internal market, unless explicitly authorised.¹⁵³ If the Member State Committee (hereinafter MSC) or the Commission consider a substance to be potentially

¹⁴⁴ REACH Regulation, Arts. 20(2) and 41(5); Emilia Korkea-aho, *Adjudicating New Governance: Deliberative Democracy in the European Union* (Routledge 2015), 118.

¹⁴⁵ REACH Regulation, Art. 20(2)

¹⁴⁶ *ibid* Arts. 41 and 51(1).

¹⁴⁷ *ibid* Arts. 51(2)-(7).

¹⁴⁸ *ibid* Arts. 40 and 51.

¹⁴⁹ ECHA, 'The role of animal testing in ensuring the safe use of chemical substances' (ECHA Fact sheet) <<https://echa.europa.eu/fr/publications/fact-sheets>> last accessed 24 August 2017.

¹⁵⁰ REACH Regulation, Art. 44.

¹⁵¹ *ibid* Art. 45.

¹⁵² *ibid* Art. 48.

¹⁵³ *ibid* Art. 56.

dangerous, they can send an application for its inclusion in the so-called candidate list for authorisation to ECHA. The decision to define a substance as SVHC is eventually either taken by the ECHA or by the Commission.¹⁵⁴ The final decision allowing the SVHC to move freely in the EU market for a limited time period is in any case always taken by the Commission.¹⁵⁵

Of course, the REACH Regulation does not stand on its own. On the contrary, apart from being one of the main actors under REACH, the European Chemicals Agency has meanwhile also been conferred powers within the context of three other regulations¹⁵⁶ dealing with the 'classification, labelling and packaging of substances and mixtures',¹⁵⁷ 'biocidal products'¹⁵⁸ and the import and export of dangerous chemicals from or to non-EU Member States.¹⁵⁹ Those remaining regulations will shortly be addressed in turn.

3.1.2. Regulation 1272/2008: Classification, Labelling and Packaging of Substances and Mixtures

The CLP Regulation mainly implements into EU law the Globally Harmonised System, in other words the UN system for classification and labelling.¹⁶⁰ Similarly to the starting point of REACH, the CLP Regulation also obliges companies to comply with its classification, labelling and packaging requirements, before products are allowed to be placed on the internal market.¹⁶¹ On top of that, it is again possible to make a distinction between three different stages: the hazard identification and classification stage, the hazard communication and labelling stage as well as the

¹⁵⁴ *ibid* Art. 59(6)-(9).

¹⁵⁵ *ibid* Art. 60(1).

¹⁵⁶ Nevertheless, its powers under REACH probably still remain the most significant ones, entailing also the most far-reaching consequences. See for example: Marco Bronckers and Yves Van Gerven, 'Legal Remedies under the EC's New Chemicals Legislation REACH: Testing a New Model of European Governance' (2009) 46(6) *Common Market Law Review* 1823, 1824; Lucas Bergkamp and DaeYoung Park, 'The Law of REACH: The Organizational and Administrative Structures' in Lucas Bergkamp (ed), *The European Union REACH Regulation for Chemicals: Law and Practice* (Oxford University Press 2013), 24.

¹⁵⁷ Regulation (EC) 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 [2008] OJ L 353/1 (hereinafter CLP Regulation).

¹⁵⁸ Regulation (EU) 528/2012 concerning the Making Available on the Market and Use of Biocidal Products [2012] OJ L 167/1 (hereinafter BP Regulation).

¹⁵⁹ Regulation (EU) 649/2012 concerning the Export and Import of Hazardous Chemicals [2012] OJ L 201/60 (hereinafter PIC Regulation).

¹⁶⁰ CLP Regulation, Recital 5.

¹⁶¹ *ibid* Art. 4(1).

packaging stage. More specifically, manufacturers, importers and downstream users are charged with the duty to gather information about the properties of a substance in order to find out whether it may be potentially hazardous.¹⁶² In that regard, Annex I refers to certain classification criteria, which, if met, will lead to a hazard being assigned to the substance.¹⁶³ In a next step, consumers need to be informed about the hazards of the substance, which is achieved through labelling requirements.¹⁶⁴ In addition, a number of packaging standards need to be adhered to in order to make sure that the substances identified as hazardous can be safely furnished to the consumers.¹⁶⁵ What is particularly important when it comes to the role of ECHA in this system is the classification and labelling inventory that applies to both substances that are subject to registration under the REACH Regulation as well as substances identified as hazardous and therefore subject to CLP requirements within the scope of the CLP Regulation.¹⁶⁶ If substances complying with the foregoing criteria are put on the internal market, producers and importers have the duty to inform ECHA in order for it to be listed in the inventory.¹⁶⁷

3.1.3. Regulation 528/2012: Biocidal Products

The BP Regulation, as the name already suggests, is concerned with the creation of an EU level playing field for biocidal products and complements the REACH and CLP Regulations.¹⁶⁸ In fact, the starting point with regard to BPs can be found in Article 15(2) of the REACH Regulation, which lists BPs as substances that are regarded as being registered as well as being exempt from the authorisation provisions of REACH in accordance with Article 56(4)(b). However, this does not mean that BPs can circulate freely in the internal market. On the contrary, just as other chemicals, BPs, or rather their active substances (hereinafter AS), are subject to an approval and authorisation procedure under the BP Regulation. Three different players are involved in the approval process: application for the approval of an AS is made to the ECHA;¹⁶⁹ NCAs are competent to evaluate ASs;¹⁷⁰ and the European Commission can approve the AS

¹⁶² *ibid* Art. 5-6.

¹⁶³ *ibid* Arts. 9 and 13.

¹⁶⁴ *ibid* Title III.

¹⁶⁵ *ibid* Title IV.

¹⁶⁶ *ibid* Art. 39.

¹⁶⁷ *ibid* Arts. 40 and 42.

¹⁶⁸ BP Regulation, Art. 2.

¹⁶⁹ *ibid* Art. 7.

¹⁷⁰ *ibid* Art. 8.

for a limited period of time.¹⁷¹ In order to be admissible to the market, BPs also need to be authorised.¹⁷² This authorisation is either granted by national authorities¹⁷³ or by the Commission upon receipt of an ECHA opinion for Union authorisations.¹⁷⁴

3.1.4. Regulation No 649/2012: Export and Import of Hazardous Chemicals

The Prior Informed Consent Regulation deals with the problems surrounding the export and import of dangerous chemicals. The PIC Regulation also implements international law obligations, namely those of the Rotterdam Convention. By imposing certain obligations on companies that want to export chemicals to or import from non-EU countries, the Regulation tries to protect the environment and human health as well as to 'promote shared responsibility and cooperative efforts in the international movement of hazardous chemicals'.¹⁷⁵ This is achieved through communication between the industry, national regulatory authorities of the exporting and importing countries and the ECHA, which coordinates between the parties.¹⁷⁶ Moreover certain chemicals listed in Annex V are banned from being exported completely.¹⁷⁷

After this outline of the reasons and problems underlying the establishment of the ECHA as well as the current framework for chemicals regulation requiring ECHA involvement, the next chapter will revolve around the internal composition of the Agency, before then examining the powers of the ECHA in more detail in chapter 3.3.

3.2. The organizational structure of the ECHA

The internal composition of the European Chemicals Agency is dealt with in Title X of the REACH Regulation. According to Article 76 of the latter, the ECHA shall consist of a Management Board,¹⁷⁸ an Executive Director,¹⁷⁹ Committees for Risk Assessment, Socio-Economic Analysis and Member States respectively,¹⁸⁰ a Forum

¹⁷¹ *ibid* Art. 9.

¹⁷² *ibid* Art. 17.

¹⁷³ *ibid* Arts. 17 and 29.

¹⁷⁴ *ibid* Arts. 17, 42 and 44.

¹⁷⁵ PIC Regulation, Art. 1

¹⁷⁶ *ibid* Arts. 7, 8 and 14(6).

¹⁷⁷ *ibid* Art. 15(2).

¹⁷⁸ REACH Regulation, Art. 76(a).

¹⁷⁹ *ibid* Art. 76(b).

¹⁸⁰ *ibid* Art. 76(c) – (e).

for Exchange of Information and Enforcement,¹⁸¹ a Secretariat,¹⁸² and very importantly a Board of Appeal.¹⁸³ This internal structure is not unusual for agencies of the European Union.¹⁸⁴

The ECHA Management Board is composed of a maximum of 34 members with voting rights, with 28 of them representing their respective Member States and a maximum of six members being appointed by the Commission. Next to that the Board comprises three representatives of interest parties as well as two persons appointed by the European Parliament, with neither of them being assigned any voting rights.¹⁸⁵ The Management Board usually takes its decision by means of a two-thirds majority of its members holding voting rights.¹⁸⁶ In general, it can be described as the 'main governing body'¹⁸⁷ of the ECHA with its primary tasks being the adoption of work programmes, the annual budget as well as reports.¹⁸⁸ Moreover, it is responsible for the appointment of the Board of Appeal,¹⁸⁹ the Committees for Risk Assessment and Socio-Economic Analysis respectively,¹⁹⁰ as well as the Executive Director,¹⁹¹ over whom it enjoys 'disciplinary authority'.¹⁹² The Executive Director for his part is mainly responsible for representing the Agency externally and carrying out the day-to-day business, ie managing the ECHA, internally.¹⁹³ As the Executive Director is, upon proposal by the Commission, appointed by the Management Board, it has a duty to report to the latter, thereby being held accountable.¹⁹⁴

As well as a newly created Biocidal Products Committee – see BP Regulation Art. 75.

¹⁸¹ *ibid* Art. 76(f).

¹⁸² *ibid* Art. 76 (g).

¹⁸³ *ibid* Art. 76(h).

¹⁸⁴ Annika Eberstein, 'The Development of EU Agencies' Informal Autonomy – a Question of Reputation' (Master Thesis, University of Leiden 2014), 27 <<https://openaccess.leidenuniv.nl/handle/1887/30167>> last accessed 24 August 2017.

¹⁸⁵ *ibid* Art. 79(1).

¹⁸⁶ *ibid* Art. 82.

¹⁸⁷ Steven Vaughan, *EU Chemicals Regulation: New Governance, Hybridity and REACH* (Edward Elgar Publishing), 68.

¹⁸⁸ REACH Regulation, Art. 78.

¹⁸⁹ *ibid* Arts. 78 and 89(3).

¹⁹⁰ *ibid* Arts. 78 and 85(1) and (2).

¹⁹¹ *ibid* Arts. 78 and 84(1).

¹⁹² Björn Rögnvaldsson Þór and Konstantinos G Margaritis, 'European Chemicals Agency and Good Governance' (2012) Human Rights and Human Welfare Working Papers 69/2012, 16 <<http://www.du.edu/korbel/hrhw/workingpapers/2012/69-rognvaldsson-2012.pdf>> last accessed 24 August 2017.

¹⁹³ REACH Regulation, Art. 83.

¹⁹⁴ *ibid* Art. 84(1).

Next to those two major governing bodies, the Agency comprises three different committees. The Committee for Risk Assessment provides opinions risks, especially within the framework of the REACH and CLP Regulation.¹⁹⁵ Similarly, the Committee for Socio-Economic Analysis issues opinions under the REACH Regulation, but focuses, as the name already states, more on the socio-economic aspects and impacts.¹⁹⁶ With regard to those two committees, upon nomination of candidates by the Member States, the Management Board will appoint the members.¹⁹⁷ The Member State Committee is slightly different, in that its members are directly appointed by the Member States.¹⁹⁸ It basically works as a kind of adjudicator between the Member States, in the sense that it tries to resolve some 'potential divergences of opinions on draft decisions'.¹⁹⁹ In addition, ECHA of course also has a Secretariat, which has grown significantly over the last years.²⁰⁰ The Secretariat mainly carries out the bureaucratic work related to the EU chemicals policy.²⁰¹ Moreover is charged with supporting the Committees and the Forum in their work as well as making sure that there is a proper coordination between those bodies.²⁰² The Forum mentioned is the Forum for Exchange of Information and Enforcement, in general responsible, as the name already indicates, for the coordinating the enforcement of the REACH Regulation by Member States.²⁰³ Although Member States have the power to appoint the members of the Forum, the latter shall 'be chosen for their role and experience in enforcement of chemicals legislation'.²⁰⁴

Last but certainly not least, the ECHA possesses its own Board of Appeal (hereinafter BoA), which consists of independent members, appointed by the Management Board.²⁰⁵ Although its members exercise their tasks independently, BoAs are generally treated as forming part and parcel of an agency.²⁰⁶ Appeals can

¹⁹⁵ *ibid* Art. 76(1)(c).

¹⁹⁶ *ibid* Art. 76(1)(d).

¹⁹⁷ *ibid* Arts. 85(1) and (2).

¹⁹⁸ *ibid* Art. 85(3).

¹⁹⁹ *ibid* Art. 76(1)(e).

²⁰⁰ Steven Vaughan, *EU Chemicals Regulation: New Governance, Hybridity and REACH* (Edward Elgar Publishing), 67.

²⁰¹ REACH Regulation, Arts. 76(1)(g) and 77(2).

²⁰² *ibid* Art. 76(1)(g).

²⁰³ *ibid* Art. 76(1)(f).

²⁰⁴ *ibid* Art. 86(1).

²⁰⁵ *ibid* Arts. 89 and 90(2)-(5).

²⁰⁶ Steven Vaughan, *EU Chemicals Regulation: New Governance, Hybridity and REACH* (Edward Elgar Publishing), 72; Marcus Navin-Jones, 'Board of Appeal: Function, Powers and Decision-making' (ppt, Keller and Heckman LLP 2014) <www.khlaw.com/Files/20434_6.Marcus%20Navin%20Jones.pdf> last accessed 24 August 2017.

be brought by natural or legal persons where they are directly addressed by the decision or where they can prove that they are directly and individually concerned.²⁰⁷ However, the BoA is only competent to hear appeals against a number of exhaustively listed decisions of the Agency.²⁰⁸ Article 91 of the REACH Regulation provides the BoA with the power to hear appeals against ECHA decisions taken during dossier and substance evaluation,²⁰⁹ on data sharing,²¹⁰ on registration of a substance after the completeness check has been carried out²¹¹ as well as decisions concerning PPOD exemptions.²¹² According to Article 77(1) of the BP Regulation, an appeal can be brought against the acceptance or rejection of a request of application or Union authorisation of an active substance²¹³, or its renewal respectively.²¹⁴ In the same vein the Board of Appeal is allowed to hear cases concerning ECHA's decision with regard to a request of technical equivalence²¹⁵ or a request concerning the wish to refer to tests or studies on vertebrates (data sharing).²¹⁶ In reaching a conclusion about the appropriateness of the decisions taken by the ECHA in the aforementioned subject areas, the BoA is allowed to fully examine the factual and legal circumstances and is not restricted to a pure legality review like the CJEU.²¹⁷ The decisions of the BoA are binding upon the Agency²¹⁸ and suspensive in their effects.²¹⁹

3.3. The tasks and powers of the ECHA

After having set out how the ECHA is composed, it is now time to examine which powers the Agency actually holds under the current chemicals legislation. This detailed elaboration is of utmost importance in order to be able to clearly analyse whether the *Meroni* doctrine, as redefined by the Court in *ESMA Short-selling*, is complied with, or

see for example: Case T-63/01 Procter & Gamble v OHIM [2002] ECLI:EU:T:2002:317, para 21.

'(...) while the Boards of Appeal enjoy a wide degree of independence in carrying out their duties, they constitute a department of the Office responsible for controlling (...) the activities of the other departments of the administration to which they belong.'

²⁰⁷ REACH Regulation, Art. 92(1).

²⁰⁸ *ibid* Art. 91.

²⁰⁹ *ibid* Art. 51.

²¹⁰ *ibid* Arts. 27(6) and 30(2)-(3).

²¹¹ *ibid* Art. 20.

²¹² *ibid* Art. 9.

²¹³ BP Regulation, Arts. 7(2) and 43(2).

²¹⁴ *ibid* Arts. 13(3) and 45(3).

²¹⁵ *ibid* Art. 54(3)-(5).

²¹⁶ *ibid* Art. 63(3) and 64(1).

²¹⁷ REACH Regulation, Art. 93(3); Marco Bronckers and Yves Van Gerven, 'Legal Remedies under the EC's New Chemicals Legislation REACH: Testing a New Model of European Governance' (2009) 46(6) *Common Market Law Review* 1823, 1845.

²¹⁸ ECHA Rules of Procedure, Art. 18 (exception: change of circumstances)

²¹⁹ REACH Regulation, Art. 91(2).

whether the Agency's powers go beyond the pale. Upon close examination of the four chemicals regulations prescribing a role for ECHA,²²⁰ it becomes apparent that the Agency mainly assumes four different roles: it provides information, it acts as an advisor in issuing guidance and providing opinions, it assumes coordinating functions and it takes legally binding decisions. Therefore, in turn, ECHA's powers will be addressed along this distinction, with the focus being on its decision-making tasks.

3.3.1. The ECHA as information-provider

One of the tasks assumed by the ECHA is to provide information about chemicals and their inherent risks. In other words, ECHA is responsible for making sure that certain information becomes publicly available and transfers it to other institutions, notably the Commission, as well as to other Member States and their NCAs.

Indeed, in light of the lack of sufficient knowledge about chemicals and of publicly available data that was characteristic for the old EU chemicals legal framework, one of the main ambitions of the REACH Regulation is to ameliorate the provision and sharing of information.²²¹ To this end, in order to pool information and make data more easily accessible, the ECHA has been appointed as the body with the main powers when it comes to ensuring that the abovementioned aims are reached. Proof of this can be found at all stages of the REACH procedure. To mention some examples, at the registration stage, NCAs are notified in case the completeness check reveals that the dossier submitted is incomplete in terms of information submitted or complete and therefore registered.²²² At the evaluation stage, ECHA informs NCAs for example of the dossiers that will be subject to a compliance check.²²³ At the authorisation stage, it is especially the decision to include a substance in the candidate list for authorization that is published.²²⁴ In general it can thus be argued that the ECHA is very keen when it comes to ensuring that all of its decisions and requests are continuously forwarded to the other actors. On top of that, with regard to its role in making information publicly available, it can generally be said that ECHA publishes all information on its website,

²²⁰ REACH Regulation, CLP Regulation, BP Regulation and PIC Regulation; see section 3.1.

²²¹ Bjorn Hansen, 'The Law of REACH: Background and Structure of REACH' in Lucas Bergkamp (ed), *The European Union REACH Regulation for Chemicals: Law and Practice* (Oxford University Press 2013), 20-21.

²²² REACH Regulation, Art. 20(2)-(4).

²²³ *ibid* Art. 41(2).

²²⁴ *ibid* Art 59(10).

except those that are confidential in character.²²⁵ Similar obligations also exist under the other three regulations. Under the CLP Regulation, the main obligation in terms of information sharing is to be found at the hazard communication stage that requires the ECHA to make the hazards of substances publicly known. This is mainly achieved through the establishment of the classification and labelling inventory.²²⁶ Moreover, in case of a request for the change of a chemical's name, the Agency has the duty to inform competent authorities of its decision.²²⁷ In the context of the BP Regulation, a 'Register for Biocidal Products' has been explicitly established, for which the ECHA is responsible.²²⁸ Besides this, the Agency needs to publish information on potential candidates for substitution before stating its view on ASs.²²⁹ Finally, under the PIC Regulation, indeed the main task of the ECHA is to make sure that information about import/export decisions are made publicly available in its database.²³⁰

3.3.2. The ECHA as advisor

With regard to ECHA's role as advisor, we need to distinguish between two different forms through which advice can be given. First of all, there is the compilation of agency guidance on the interpretation and implementation of chemicals legislation and secondly, the provision of opinions and recommendations to the Commission (as well as Member States). While both of those instruments are non-binding in nature, the latter can lead to the adoption of 'binding implementing rules' by the Commission.²³¹ Moreover, even with regard to the first type of guidance, it has been held that, despite their non-binding nature and their non-reviewability, in light of the principle of sincere cooperation, Member States' competent authorities and courts 'shall make every effort to comply with those guidelines and recommendations'.²³²

²²⁵ Tony Musu, 'The European Chemicals Agency: keystone of REACH' (2008) 34 *HESA Newsletter* 8, 9; See also: <<https://echa.europa.eu/de/home>> last accessed 24 August 2017.

²²⁶ CLP Regulation, Art. 42.

²²⁷ *ibid* Art. 24(5).

²²⁸ BP Regulation, Art. 71(1).

²²⁹ *ibid* Art. 10(3).

²³⁰ PIC Regulation.

²³¹ Edoardo Chiti, 'European Agencies' Rulemaking: Powers, Procedures and Assessment' (2013) 19(1) *European Law Journal* 93, 96.

²³² Edoardo Chiti, 'European Agencies' Rulemaking: Powers, Procedures and Assessment' (2013) 19(1) *European Law Journal* 93, 96; Letizia Gianni, 'Constitutionality, Powers and Legitimacy of EU Agencies or Agency-Like Bodies' (European University Institute Conference Report, Florence 2016), 15 <<https://tarn.maastrichtuniversity.nl/full-report-florence-conference-available/>> last accessed 24 August 2017.

Proof of the Agency's role in guiding and advising is to be found in the REACH Regulation. ECHA's main advisory powers probably arise at the authorisation stage where it can be said to provide major input for the Commission's final decision as to whether SVHC should be allowed to circulate freely in the internal market.²³³ As has been explained earlier on, ECHA will determine, on the basis of the criteria provided for in Article 57 and in accordance with Article 59, whether a substance should be put on the candidate list for authorisation or not. This act is often defined as constituting an opinion, on the basis of which the Commission can in the end take the final decision as to whether a SVHC should be allowed on the internal market temporarily.²³⁴ However, over time it has become apparent that it is not appropriate to define this Agency action as being of advisory nature only. This is so because, as was concluded in for example *Rütgers v. ECHA*, ECHA's decision to put a substance on the candidate list has legal consequences on its own, mostly in terms of triggering information requirements, and does therefore not constitute a 'preparatory act' only.²³⁵ Hence, when it comes to this aspect of the procedure, ECHA acts on the one hand as an advisor to the Commission and on the other hand it has decision-making powers on its own, which is why the issue will be discussed again in more detail in section 3.3.4. concerning ECHA's decision-making powers. On top of this, the Agency has the task to provide technical guidance in order to facilitate the application, interpretation and operation of the Regulation. Guidance documents are generally published on its website.²³⁶

This latter aspect also holds true with regard to the CLP, the BP and the PIC Regulation.²³⁷ On top of that, under the CLP Regulation, ECHA shall formulate an opinion concerning a request for harmonised classification and labelling of a substance and send it to the Commission.²³⁸ Next, when it comes to BPs, in the context of hazard identification and classification, the ECHA takes the NCA's evaluations into account in order to adopt an opinion on the approval or renewal of approval of active substances,

²³³ REACH Regulation, Art. 64.

²³⁴ To be witnessed from the wording used in the REACH Regulation.

²³⁵ REACH Regulation, Arts. 7(2), 31(1)(c), 31(3)(b) and 33(1) and (2); Case T-96/10 *Rütgers Germany GmbH v. ECHA* [2013] ECLI:EU:T:2013:109, para 34.

²³⁶ REACH Regulation, Art. 77(2).

²³⁷ CLP Regulation, Art. 50; BP Regulation, Arts. 11, 24, 40, 42(2), 54(8), 67(1)(g); PIC Regulation, Art. 6(1)(c) – (e).

²³⁸ CLP Regulation, Art. 37(1)-(4).

which it subsequently sends to the Commission.²³⁹ At the actual authorisation stage, the ECHA will only be allowed to give its advice in case of an application for a Union authorisation (or its renewal).²⁴⁰ On top of that, Article 38 lays down a general obligation for ECHA to issue an opinion upon request by the Commission within the scope of a mutual recognition procedure.²⁴¹ Finally, when it comes to exports and imports of hazardous substances, besides its general power to produce guidance, the ECHA does not have any special advisory tasks under the PIC Regulation.²⁴²

3.3.3. The ECHA as administrator and coordinator

Under some circumstances, the ECHA may serve as a kind of manager or coordinator. In that regard, as has already been mentioned above, it is important to understand that the REACH brought about an important change, namely the placing in the hands of the Member States of substance evaluation.²⁴³ However, this does not rule out every involvement of the ECHA. Indeed, ECHA continues to carry out a coordinating role, which consists in cooperating with Member States national authorities in for example establishing the draft CoRoAP wherein it prioritizes substances on the basis of the seriousness of their potential harmful effects for human health and the environment.²⁴⁴ Moreover, Article 75(1) more generally confirms the Agency's task of 'managing and (...) carrying out the technical, scientific and administrative aspects of this Regulation (...)'. The BP Regulation explicitly provides for the setting up of a coordination group, which shall deal with requests for authorizing mutual recognition of BPs.²⁴⁵ Moreover, as under REACH, the Agency coordinates the evaluation of dossiers.²⁴⁶ Talking about the other two Regulations, neither the CLP nor the PIC Regulation provide for a specific role for the ECHA as coordinator.

²³⁹ BP Regulation, Arts. 8(4) and 15(2) .

In drafting its opinion, the agency, in accordance with Art. 10(2) is obliged to take into account whether the active substance could be subject to substitution.

Next to the applicant having the power to ask for a renewal of the authorisation, the Commission also has the power to review the approval of an AS under certain conditions (Art. 15(2) BP Regulation). In this context, the ECHA has an advisory power as well.

²⁴⁰ *ibid* Arts. 44(3) and 46(3); see also: Art. 46(3) for renewal applications.

²⁴¹ *ibid* Art. 38(1).

²⁴² PIC Regulation, Art. 6(1)(c) – (e) .

²⁴³ Christian Hey, Klaus Jacob and Axel Volkery, 'Better Regulation by new Governance Hybrids? Governance Models and the Reform of European Chemicals Policy' (2007) 15(18) *Journal of Cleaner Production* 1859, 1864.

²⁴⁴ REACH Regulation, Arts. 44(1) and 45(1).

²⁴⁵ BP Regulation, Art. 35(1).

²⁴⁶ *ibid* Art. 90(1).

3.3.4. The ECHA as decision-maker

ECHA is one of the few EU agencies that is allowed to take legally binding decisions in certain situations. Under the REACH regime, ECHA's decision-making powers can mainly be found at the registration stage, as well as at the evaluation and authorisation stage, where decision-making powers are divided between the Agency and the Commission.²⁴⁷ In line with the REACH principle 'no data, no market', substances need to be registered before they can access the internal market.²⁴⁸ An exception to this general rule can be found in Article 9 REACH Regulation in case of substances with the aim of 'product or process oriented research development' (hereinafter PPORD). In case a PPORD notification is submitted to ECHA, ECHA's decision-making powers come in at two different levels. Firstly, it can decide to impose conditions in order to make sure that the use of the substance remains within the limits of the Regulation.²⁴⁹ Secondly, it has the power to grant a five-year extension of the exemption.²⁵⁰ Next, at the actual registration stage, ECHA's most important power lies in its review of whether the registration or the update thereof is complete or not. This completeness check is carried out on the basis of clearly defined criteria that are listed in Article 20(2).²⁵¹ Those criteria relate most importantly to the type of information to be included in the dossiers and the fee to be paid.²⁵² The outcome of the completeness check is of utmost important, because a rejection at this stage might already prevent substances from being manufactured in or imported to the market.²⁵³ In order to facilitate the provision of information, REACH provides for certain data-sharing mechanisms. On the one hand, in case the registration of a certain substance goes back in time no more than twelve years, applicants are obliged to request data of previous registrants where animal testing was used, and may do so in all other cases.²⁵⁴ ECHA's tasks come into play where the applicant and the previous registrant(s) fail to reach an agreement. In that case, within one month upon notification of the just mentioned failure, ECHA can either give permission to refer to previous information, or reject the application for sharing of existing data altogether.²⁵⁵ On the other hand, with the REACH Regulation,

²⁴⁷ Marco Bronckers and Yves Van Gerven, 'Legal Remedies under the EC's New Chemicals Legislation REACH: Testing a New Model of European Governance' (2009) 46(6) *Common Market Law Review* 1823, 1836.

²⁴⁸ REACH Regulation, Art. 5.

²⁴⁹ *ibid* Art. 9(4).

²⁵⁰ *ibid* Art. 9(7).

²⁵¹ *ibid* Art. 20.

²⁵² *ibid* Arts. 10, 12, 6(4), 7(1).

²⁵³ *ibid* Art. 20(2).

²⁵⁴ *ibid* Art. 27(1).

²⁵⁵ *ibid* Art. 27(6).

a very important data sharing system, called SIEF, was established.²⁵⁶ The members of the different SIEFs shall communicate with each other in order to produce information required for the completeness check in the most efficient way possible and avoid unnecessary animal testing.²⁵⁷ If a relevant study does already exist, disputes can arise in case the data owner refuses to provide the applicant with the data. In that case, ECHA has the power to allow the registrant to move on in the registration process without fulfilling all of the information requirements or alternatively, if the data owner gave data access to other SIEF participants, allow those to transfer them to the applicant.²⁵⁸ If no relevant studies exist, they shall make sure that only one of the participants carries out the tests on behalf of the others.²⁵⁹ Again, in case of disagreement, ECHA can decide who shall perform the testing.²⁶⁰

For at least 5% of registrations, a more intrusive compliance check will be carried out based on the criteria of Article 41(1).²⁶¹ In that case, the ECHA may as well have the power to take a decision affecting third parties. More specifically, if, no changes are suggested upon sending the draft decision concerning the compliance of the information submitted with the standards of REACH to the NCAs within 30 days, the ECHA can take the final decision.²⁶² The same holds true for situations where NCAs indeed do not unconditionally accept the draft decision, but where subsequently a unanimous decision can be adopted in ECHA's MSC within 60 days of referral.²⁶³ In the absence thereof, the Commission will be the final decision-maker.²⁶⁴ Next to this, still in the context of dossier evaluation, when it comes to examination of proposals involving testing on vertebrate animals, the ECHA has the power to either approve, reject or modify them and may require the submission of additional information.²⁶⁵ In taking its decision, the Agency considers relevant information submitted by third parties.²⁶⁶ Just as for the compliance check, the decision is taken in accordance with the Article 51 procedure.²⁶⁷ On top of those individualized decisions, ECHA is also

²⁵⁶ Substance Information Exchange Forum.

²⁵⁷ *ibid* Arts. 29(2)(a) and 30(1).

²⁵⁸ *ibid* Art. 30(3).

²⁵⁹ *ibid* Art. 30(2).

²⁶⁰ *ibid*.

²⁶¹ *ibid* Art. 41(5).

²⁶² *ibid* Art. 51(2)-(3).

²⁶³ *ibid* Art. 51(4) and (6).

²⁶⁴ *ibid* Art. 51(7).

²⁶⁵ *ibid* Art. 40(3).

²⁶⁶ *ibid* Art. 40(2).

²⁶⁷ *ibid* Art. 51(1).

allowed to take more general decisions, as can be witnessed from its power to adopt a Community Rolling Action Plan, although in consultation with Member States' competent authorities, which prioritises the substances to be evaluated at national level on the basis of certain criteria provided for in Article 44(1). In that regard, the Agency may again be competent to adopt the decision, on the basis of an opinion by the MSC, as to how the findings made by the NCAs during the evaluation process at national level should be used.²⁶⁸ This decision will again be taken in accordance with the Article 51 procedure just elaborated.²⁶⁹

Finally, one of the most important decisions ECHA can take is the one to add a substance to the candidate list for authorisation and thereby define it as a potential substance of very high concern that should no longer be placed on the market unless authorisation is explicitly granted.²⁷⁰ In taking this decision, the Agency is guided by the criteria of Article 57. The procedure specifically gives ECHA the power to take the "final" decision if certain conditions are fulfilled: first of all, it must have sent its draft decision to Member States within 30 days upon receipt of the NCA's conclusions;²⁷¹ and secondly, it must have published its draft decision and given interested parties the opportunity to comment for a time period of 60 days.²⁷² If, after this time period elapses, no comments are given, ECHA can decide to qualify the substance as being of potentially very high concern.²⁷³ If Member States have commented, the dossier is referred to the MSC, which needs to come to a unanimous decision within 15 days in order for ECHA to have the final say.²⁷⁴ If they do not succeed, the Commission will be the institution to decide whether or not to add a substance to the candidate list.²⁷⁵ However, in the end it needs to be borne in mind that the final decision on whether a substance may be used in the EU always depends on the Commission.²⁷⁶ Indeed, ECHA's decision-making powers under Article 59 of the REACH are the ones that have been subject to most of the challenges before the CJEU. In that regard, cases such as

²⁶⁸ *ibid* Art. 44(2).

²⁶⁹ *ibid* Art. 52(1) and (2).

²⁷⁰ *ibid* Art. 59(1).

²⁷¹ *ibid* Art. 59(3).

²⁷² *ibid* Art. 59(4) and (5).

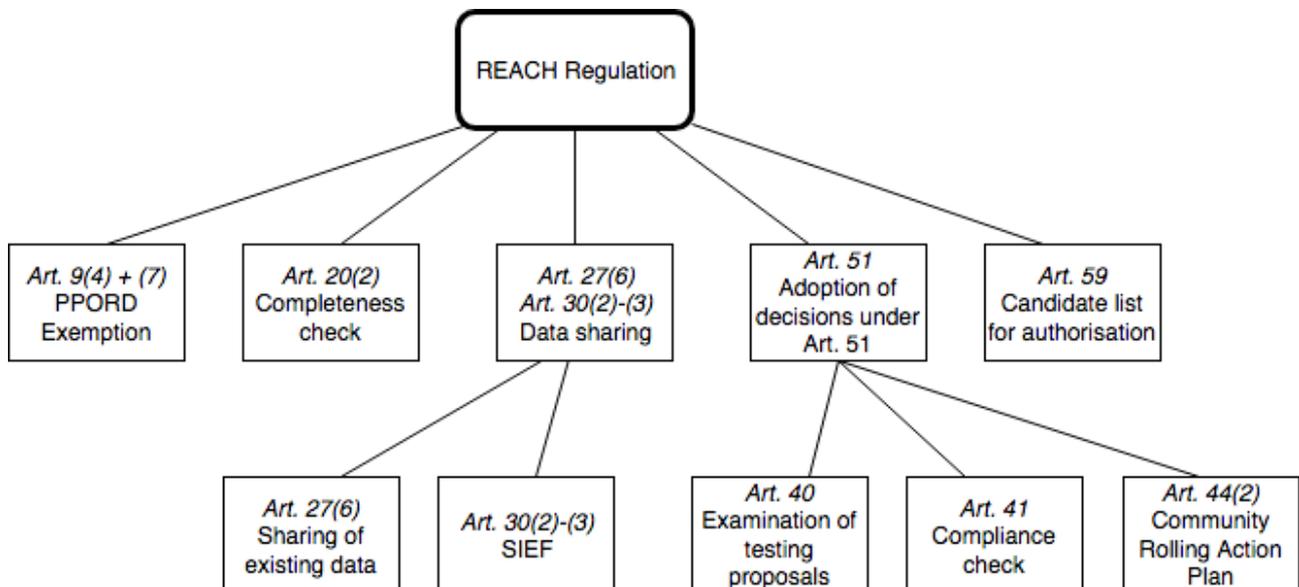
²⁷³ *ibid* Art. 59(6).

²⁷⁴ *ibid* Art. 59(7) and (8).

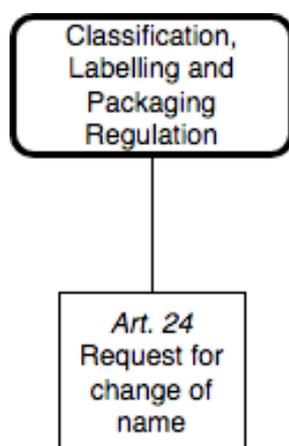
²⁷⁵ *ibid* Art. 59(9).

²⁷⁶ REACH Regulation, Art. 60(1).

Rütgers Germany and Others v. ECHA,²⁷⁷ or *Polynt and Sitre v. ECHA* are of considerable importance, and will be further elaborated on in chapter four.



Turning to CLP, one of the most important decision-making powers of the Agency is the one to approve or reject a request for change of name.²⁷⁸ In order for such a request to succeed, the applicants need to make sure that the criteria of Part 1 of Annex 1 are fulfilled and must prove that in the absence of the approval of an alternative name to be used publicly, ‘the confidential nature of his business’ would be at risk.²⁷⁹



²⁷⁷ Case T-96/10 *Rütgers Germany GmbH v. ECHA* [2013] ECLI:EU:T:2013:109; *Polynt SPA and Sitre Srl v. ECHA* [2015] ECLI:EU:T:2015:254.

²⁷⁸ CLP Regulation, Art. 24.

²⁷⁹ *ibid* Art. 24(1).

Under the BP Regulation, the Agency's decision-making powers come in at the level of approval, where ECHA can accept or reject the application for approval of an active substance or its renewal respectively. ECHA's decision depends on whether the applicant succeeds in paying the fees within 30 days upon the submission of the application.²⁸⁰ Similarly, where the applicant applies for a Union authorisation, ie an authorisation covering as a rule of thumb the whole territory of the EU, the ECHA can accept or reject the application for such a Union authorisation or the renewal thereof under the same conditions.²⁸¹ Moreover, the Agency, upon application, is in charge of establishing the similarity, both in terms of composition and attached hazards, between different ASs.²⁸² This decision is taken upon receipt of a dossier containing certain prescribed information.²⁸³ It is performed after approval by the ECHA of the application of the reference source, but needs to take place before authorisation, meaning that only if the ECHA is favourable in granting the status of technical equivalence, will the alternative source be taken into account at the authorisation stage.²⁸⁴ Lastly, ECHA is competent to decide to either grant or refuse applicants permission to refer to a study involving the testing of vertebrates, in case a request for data-sharing has been denied. There are no specific criteria that need to be considered by the Agency to come to a conclusion within 60 days, however, each party's efforts should be taken into account.²⁸⁵

²⁸⁰ BP Regulation, Arts. 7(2) and 13(3).

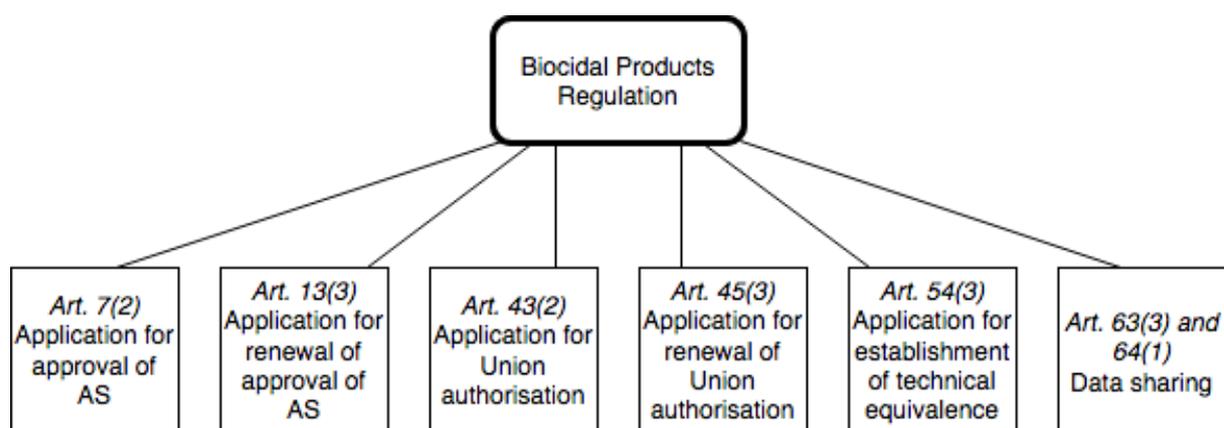
²⁸¹ *ibid* Art. 43(2) and 45(3).

²⁸² *ibid* Art. 54(3).

²⁸³ *ibid* Art. 19(1)(c).

²⁸⁴ ECHA, 'Guidance on the Biocidal Products Regulation: Volume V Guidance on applications for technical equivalence' (ECHA Guidance 2017) <<https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation>> last accessed 24 August 2017.

²⁸⁵ BP Regulation, Arts. 63(3) and 64(1).



Finally, the PIC Regulation does not invest ECHA with the power to take legally binding decisions.

3.4. Conclusion

It can thus be concluded that the ECHA has decision-making powers under three of the four Regulations it is involved in, namely the REACH, BP and the CLP Regulation. On top of that it also provides for advice and acts as an information-provider as well as a coordinator for EU chemicals policy.

With reference to the categorisation of agencies in chapter one and building on the foregoing detailed description of ECHA's powers, it is finally possible to identify whether the ECHA can be defined as an ordinary, a pre-decision-making, a decision-making or a regulatory agency. Indeed, it has been concluded that ECHA has powers that can be described as ordinary in nature, namely when it acts in its role as information provider in and manager of the different chemical legislations. On top of that, the Agency also provides both competent authorities of the Member States as well as the Commission with opinions and guidelines, which are, in light of the extremely specific and technical nature of issues relating to chemicals, particularly compelling upon its recipients. Whether this, on its own, would be sufficient in order to define ECHA has an agency having pre-decision-making powers, ie *de facto* decision-making powers, is questionable. However, in light of the fact that the Agency is clearly provided with real decision-making powers in the context of the REACH, the CLP and

the BP Regulations on top of its power to issue opinions, this question fades into the background. The scope of these areas of competences does not go as far as to transform ECHA into a real regulatory agency with broad discretionary powers of general application. It can thus reasonably be concluded that the ECHA can be classified as a decision-making agency. In turn, it will therefore finally be analysed whether a decision-making agency, such as the ECHA, in the execution of its tasks, complies with the *Meroni* non-delegation doctrine.

Chapter 4: The European Chemicals Agency and the anti-delegation doctrine: an analysis

The extent of the powers delegated to the European Chemicals Agency is rather debatable in light of the strict limits to agency delegation developed by the Court in *Meroni*. Indeed, as Emilia Korkea-aho rightly concluded, '(t)he ECHA is the first EU agency to seriously test the boundaries of the *Meroni* principle'.²⁸⁶ This chapter therefore tries to finally answer the question whether the non-delegation doctrine is complied with in the specific case of the ECHA. When looking at the Court's ruling in both *Meroni* and *ESMA Short-selling* together, it becomes apparent that the main requirements for *agencification* to be legal can be arranged at two different levels. First of all, there are criteria relating to the scope of powers delegated and secondly there are criteria relating to the need for sufficient control of the Agency when executing its tasks.²⁸⁷ Indeed, as already established, the empowerment of agencies does not engender the characteristics of a traditional delegation,²⁸⁸ which is why the first two conditions of the *Meroni* doctrine relating to the delegation of powers as such²⁸⁹ are not relevant for the present analysis. Therefore, in turn, the elements that point to or against compliance with the anti-delegation doctrine will be considered along the line of this distinction between the scope of powers and their control.

4.1. The scope of the delegated powers

The scope of powers that can legitimately be delegated to agencies has been limited in *Meroni* to clearly defined executive powers at the dispense of discretionary ones.²⁹⁰ At first sight, this condition seems to rule out any transfer of real discretion and therefore seems to be at odds with the delegation of real decision-making powers to the ECHA. However, as we have seen earlier on, some flexibility may have been added to this requirement. Indeed, in *ESMA Short-selling* the transfer of some discretionary

²⁸⁶ Emilia Korkea-aho, *Adjudicating New Governance: Deliberative Democracy in the European Union* (Routledge 2015), 127.

²⁸⁷ Case 9/56 *Meroni & Co, Industrie Matallurgische S.P.A. v. High Authority* [1957–1958] ECLI:EU:C:1958:7, 152; Case C-270/12 *The United Kingdom v. Council and European Parliament* [2014] ECLI:EU:C:2014:18, paras 45 and 53.

²⁸⁸ See section 2.1.

²⁸⁹ Those limits are that (1) the Agency cannot be delegated more powers than the delegating authority enjoyed itself and that (2) the Agency's needs to carry out the tasks under the same conditions as the delegating authority. Case 9/56 *Meroni & Co, Industrie Matallurgische S.P.A. v. High Authority* [1957–1958] ECLI:EU:C:1958:7.

²⁹⁰ Case 9/56 *Meroni & Co, Industrie Matallurgische S.P.A. v. High Authority* [1957–1958] ECLI:EU:C:1958:7, 152.

powers has been judged legal, as long as circumscribed by clear conditions and criteria. In other words, it is still not allowed for agencies to carry out tasks providing for a broad room of manoeuvre, however, some discretionary and precisely delineated judgement can be exercised by EU agencies.²⁹¹ This finding is of considerable importance because it gradually brings law and practice in the sphere of agencies more in line.²⁹² However, it is overshadowed by the formal reconfirmation of the *Meroni* judgment. This explains the need to examine ECHA's compliance with both the traditional *Meroni* doctrine and the updated one, sometimes called *Meroni 2.0*.²⁹³ In turn, the scope of ECHA's decision-making powers as explained in section 3.3.4. will be tested against both of those variations.²⁹⁴

First of all, ECHA enjoys decision-making powers when carrying out the completeness check under the REACH Regulation.²⁹⁵ Upon close examination it becomes apparent that in deciding whether the dossier submitted by a producer or importer is complete, the ECHA is indeed guided by clear conditions that can be found mainly in Articles 10 and 12.²⁹⁶ In general, those criteria are very technical and straightforward in nature in that they explicitly enumerate the information that needs to be present in order for registration to succeed and do not therefore require an in-depth analysis by the Agency. Moreover it is explicitly stated that ECHA does not assess 'the quality or the adequacy of any data or justifications submitted'.²⁹⁷ Quite clearly, in light of the vast amount of conditions circumscribing ECHA's powers, the modified *Meroni* doctrine would be complied with when it comes to the nature of powers. Similarly, as ECHA merely conducts a technical assessment without balancing different options against each other, the institutional balance of the EU is not affected and no discretion is granted. Therefore, the traditional *Meroni* doctrine is not violated either. *Prima facie*, the same holds arguably true for the PPORD exemption that may be judged applicable

²⁹¹ Case C-270/12 *The United Kingdom v. Council and European Parliament* [2014] ECLI:EU:C:2014:18, para 45.

²⁹² Merijn Chamon, 'EU Agencies: Does the *Meroni* Doctrine Make Sense?' (2010) 17(1) *Maastricht Journal of European and Comparative Law* 281, 291; Marta Simoncini, 'The Erosion of the *Meroni* Doctrine: The Case of the European Aviation Safety Agency' (2015) 21(2) *European Public Law* 309, 317-318.

²⁹³ Ellen Vos, 'EU Agencies on the Move: Challenges Ahead' (2016) SIEPS Working Paper, 20 (forthcoming).

²⁹⁴ It needs to be borne in mind that there are no clear-cut definitions of the requirements provided for in *Meroni*. Various authors have applied the criteria differently. The present analysis is based solely on the aspects discussed in *Meroni* by the Court and the author's understanding of the concepts of 'discretionary' or 'clearly defined executive powers'.

²⁹⁵ REACH Regulation, Art. 20(2).

²⁹⁶ *ibid* Arts. 10 and 12. See also: REACH Regulation, Arts. 17 and 18; Art 6(4), 7(1) and (5), 17(2), 18(2).

²⁹⁷ *ibid* Art. 20(2).

by the ECHA after having carried out a completeness check.²⁹⁸ Again, clear and technical criteria in Article 9(2) need to be fulfilled. However, on top of that, the Agency also has the power to impose certain additional conditions on the applicant.²⁹⁹ Those conditions are intended to make sure that the requirements of Article 9(4) are complied with. Next, ECHA is also entitled to grant a 5 years extension of the exemption.³⁰⁰ Speaking about the *Meroni* doctrine in the traditional sense, even though the conditions listed in Article 9(2) and the aims mentioned in Article 9(4) guide the Agency in deciding about additional conditions and time periods, there is still some room for considering whether there are enough indications that would justify such a decision and what conditions should be imposed. Therefore, it is questionable whether those two decision-making powers can be held compatible with the *Meroni* ruling. On the contrary, the foregoing can definitely be judged to sufficiently circumscribe ECHA's powers and does not confer upon the Agency a 'very large measure of discretion',³⁰¹ which was held to be decisive in *ESMA Short-selling*.

Another area ECHA takes legally binding decisions in is data sharing. First, with regard to the decision to allow an applicant to refer to information of another registrant in case no agreement could be reached,³⁰² Article 27(6) requires ECHA to assess whether the proportionate share has been paid to the original registrant. In doing so it is to take into account of the guidance produced under Article 77(2)(g). However, in deciding whether something is proportionate or not, some balancing will always be involved. As ECHA's task is on the one hand very technical, but on the other hand does not seem to be completely without discretion either, it very much depends on the strictness of the *Meroni* reading whether this is acceptable or not. The same holds true for ECHA's powers in the SIEF context, which are on the one hand very technical, but on the other hand provide some leeway in deciding who is to conduct a certain study or whether a study needs to be repeated.³⁰³ In any case, the criteria provided for in Article 77(2)(g), the involvement of ECHA as a means of last resort as well as the

²⁹⁸ *ibid* Art. 9(3).

²⁹⁹ *ibid* Art. 9(4).

³⁰⁰ *ibid* Art. 9(7).

³⁰¹ Case C-270/12 *The United Kingdom v. Council and European Parliament* [2014] ECLI:EU:C:2014:18, para 54.

³⁰² REACH Regulation, Art. 27(5).

³⁰³ *ibid* Art. 30(2)-(3).

technical nature of those decision-making powers will suffice to make it compatible with the *ESMA* requirements.

Turning to the decisions taken under the Article 51 procedure, first the compliance check needs to be addressed. In carrying out this check, ECHA has the duty to respect the specific requirements and criteria of Article 41(1) and (5), Annexes I and III as well as Annexes VII-XI.³⁰⁴ It is limited in both its power to select specific dossiers for compliance checking and in carrying out the compliance check. On top of that, Article 51 even describes thoroughly how the compliance check is to be conducted. Those criteria are necessarily enough to ensure that the power delegated to ECHA is not too extensive to comply with the *Meroni 2.0.* doctrine. When it comes to the traditional non-delegation doctrine, it can be observed that the substantive and procedural conditions are indeed not as straightforward and technical as the ones governing the completeness check and leave therefore a little room for discretion for ECHA. Therefore, the traditional *Meroni* doctrine would probably be breached.

Moreover, ECHA seems to enjoy some discretion when it comes to its powers with regard to testing proposals. In examining the proposals for animal testing submitted to it, ECHA is guided in choosing which proposals it needs to review with priority.³⁰⁵ However, in actually examining the proposal and taking the draft decision, it is only limited by the requirement to take into account the scientific information that may be submitted by third parties within 45 days upon publication.³⁰⁶ The final decision is again taken in accordance with Article 51, meaning that the Commission will only be involved in case amendments of the draft decision are proposed by Member States and no unanimous agreement in the MSC could be reached.³⁰⁷ Indeed, in this case, the ECHA is clearly in the driving seat when drafting its decision as to the performance of tests on vertebrates and can be said to be required to take into account different interests and balance them against each other. Consequently, should no amendments be proposed, ECHA is in possession of discretionary powers. Even if the final decision is taken upon consideration of the draft by the MSC, ECHA has a considerable influence

³⁰⁴ *ibid* Art. 41.

³⁰⁵ *ibid* Art. 40(1).

³⁰⁶ *ibid* Art. 40(2).

³⁰⁷ *ibid* Art. 51(7).

on the outcome. This is also illustrated by its power to adapt ‘the conditions under which the test is to be carried out’ in its draft decision.³⁰⁸ This probably contradicts the traditional *Meroni* doctrine. On the contrary, in light of the procedural limits set by Article 51 and the criteria for prioritisation in Article 40(1) the powers are most certainly sufficiently delineated and circumscribed in order to comply with the modified doctrine.

At the substance evaluation stage, ECHA’s power to adopt the final Community Rolling Action Plan is also of tremendous importance. Even though the Agency is not involved in the evaluation of the chemical per se and can thus not contribute to the content of the decision,³⁰⁹ it can decide to either adopt it or not where no comments are submitted or where upon receipt of comments by the Member States, the draft CoRoAP has been unanimously agreed upon in the MSC.³¹⁰ Indeed, in case of referral of the draft CoRoAP to the MSC, the Agency can get indirectly involved in the evaluation process by amending the plan in light of the comments received by Member States.³¹¹ However, despite this eventual indirect involvement in the substance evaluation, it cannot be concluded that there is discretion in the hands of the ECHA. On the contrary, ECHA needs to comply with the procedural criteria laid down especially in Article 51 and needs to stick to the comments proposed by Member States.³¹² Moreover, the substance evaluation as such is to be performed by NCAs.³¹³ Therefore, both the requirements established in *Meroni* as well as in *ESMA Short-selling* should be complied with.

Finally, as already hinted at above when mentioning the high number of challenges brought before the CJEU relating to ECHA’s practice of deciding to add a certain substance considered to be of high concern to the candidate list for authorisation, the compatibility of this action with the anti-delegation doctrine is not as clear-cut, even though ECHA’s powers are delineated by a large number of criteria and conditions. In that regard, it first of all needs to be borne in mind that ECHA actually only has the power to adopt the decision adding a substance to Annex XIV if no amendments have

³⁰⁸ *ibid* Art. 40(3)(b).

³⁰⁹ *ibid* Art. 45(1).

³¹⁰ *ibid* Art. 51(1), (3) and (6).

³¹¹ *ibid* Art. 51(4).

³¹² *ibid*.

³¹³ *ibid* Art. 45.

been proposed by NCAs or alternatively if the decision in conjunction with the proposed changes is unanimously adopted in the MSC.³¹⁴ In other words, ECHA's decision-making powers mostly come in in situations where there is an overall agreement as to the hazardous nature of certain substances to begin with. Next to this, Article 57 provides for conditions which substances need to fulfil in order to be characterised as being of high concern. However, contrary to conditions such as those provided for with regard to the registration of a substance, the present criteria leave more room for discretion to ECHA, which leads to the conclusion that it infringes the traditional *Meroni* requirements. Indeed, when analysing the case law concerning ECHA's powers with regard to candidate lists, it becomes apparent that the Court seems to have concluded that ECHA enjoys broad discretionary powers in taking its decision, which indicates that this Article 59 power would also be at odds with the *ESMA Short-selling* judgment.³¹⁵ More specifically, in cases such as *Rütgers v. ECHA* or *Polynt and Sitre v. ECHA*, the Court concluded that ECHA has

(...) broad discretion in a (sphere) which entails political, economic and social choices on its part, and in which it is called upon to undertake complex assessments. The legality of a measure adopted in that (sphere) can be affected only if the measure is manifestly inappropriate having regard to the objective which the legislature seeks to pursue.³¹⁶

This goes so far as to lead academics to conclude that 'the transfer of broad discretion to agencies is now established case law of the Court'.³¹⁷ However, this conclusion cannot simply be drawn. In fact there is a need to take into account the different contexts in which the *ECHA* judgments and the *ESMA* judgment have been made. In *ESMA*, the UK specifically invoked the violation of the anti-delegation doctrine.³¹⁸ On the contrary, the issue at stake in the *ECHA* judgments was not the violation of the non-delegation doctrine, but on the contrary the applicants invoked a

³¹⁴ *ibid* Art. 59(5)-(9).

³¹⁵ REACH Regulation, Art. 57.

³¹⁶ Case T-96/10 *Rütgers Germany GmbH v. ECHA* [2013] ECLI:EU:T:2013:109, para 134; Case T-134/13, *Polynt SPA and Sitre Srl v. ECHA* [2015] ECLI:EU:T:2015:254, para 105.

³¹⁷ Herwig CH Hofmann, 'European Regulatory Union? The Role of Agencies and Standards' in Panos Koutrakos and Jukka Snell (eds), *Research Handbook on the Law of the EU's Internal Market* (Edward Elgar Publishing 2017), 469.

³¹⁸ Case C-270/12 *The United Kingdom v. Council and European Parliament* [2014] ECLI:EU:C:2014:18, paras 27-34.

breach of the principle of proportionality in the sense that they considered ECHA's decision to define a substance as being of potentially very high concern to be manifestly inappropriate in relation to the objectives of the Regulation.³¹⁹ Indeed, when it comes to claims concerning this general principle of EU law, although usually with regard to EU institutions in general, it is common practice to refer the presence of broad discretion in order to make sure that the scope of judicial review remains limited.³²⁰ This is because the CJEU is not competent to substitute the original technical assessment for its own, generally less proficient, evaluation.³²¹ In fact, the general practice of limiting its review to 'manifest errors of assessment' is also mentioned in the cases referred to above.³²² Hence, in the end, the Court might just have taken over a general EU law statement without effectively having had the intention to conclude that ECHA's powers enjoyed under Article 59 entail a very large measure of discretion in the *ESMA Short-selling* meaning of the concept. This might thus again be another proof for the inconsistency that exists at EU level in construing different judge-made concepts, such as 'clearly defined executive powers' as opposed to 'discretionary powers', or the just mentioned 'large measure of discretion'.³²³ In that regard, it might also be helpful to actually compare the degree of discretion left to ECHA under the conditions of Article 57 and to ESMA in the context of Article 28 of the Short Selling Regulation respectively, which is legitimate, because, as Advocate General Jääskinen concluded, the 'ESMA is (...) a decision-making agency of the same kind as (...) the European Chemicals Agency'.³²⁴ Such a comparison reveals that it is reasonable to argue that ESMA has slightly more discretion in carrying out its tasks under Article 28 than ECHA does when performing its Article 59 powers. According to Article 28 of the Short Selling Regulation, the ESMA can only act where a number of conditions are met, the most important ones being: the presence of circumstances that threaten the 'orderly functioning and integrity of financial markets or (...) the stability (...) of the financial system of the European Union'; the existence of cross-border implications; and the lack of (adequate) measures taken by other competent authorities.³²⁵

³¹⁹ Case T-96/10 *Rütgers Germany GmbH v. ECHA* [2013] ECLI:EU:T:2013:109, para 132; Case T-134/13, *Polynt SPA and Sitre Srl v. ECHA* [2015] ECLI:EU:T:2015:254, para 103.

³²⁰ Alina Kaczorowska, *European Union Law* (Routledge 2013), 185-186.

³²¹ Marco Bronckers and Yves Van Gerven, 'Legal Remedies under the EC's New Chemicals Legislation REACH: Testing a New Model of European Governance' (2009) 46(6) *Common Market Law Review* 1823, 1844-45.

³²² Case T-96/10 *Rütgers Germany GmbH v. ECHA* [2013] ECLI:EU:T:2013:109, para 133; Case T-134/13, *Polynt SPA and Sitre Srl v. ECHA* [2015] ECLI:EU:T:2015:254, para 104.

³²³ see section 2.5.

³²⁴ C-270/12 *The United Kingdom v. Council and European Parliament* [2014] ECLI:EU:C:2014:18 (Opinion of AG Jääskinen), para 23.

³²⁵ Short Selling Regulation, Art. 28(1).

Moreover, the measure taken should be preferably such as to significantly address the threat or significantly improve competent authorities' possibility to do so.³²⁶ The 'risk of regulatory arbitrage' should be avoided and the 'efficiency of the financial markets' should be preserved.³²⁷ Finally, the ESMA also has the duty to consult the ESRB, inform NCAs and conduct reviews.³²⁸ In the case of ECHA, as already mentioned, Article 59 taken in conjunction with Article 57 circumscribes ECHA's powers by strict time limits,³²⁹ by requiring it to publish the submission of an Annex XIV dossier and allow third parties to submit comments;³³⁰ by limiting its decision-making powers to situations where no observations were submitted,³³¹ or where in the contrary, the proposed amendments were decided upon unanimously in the MSC;³³² and by providing for a list of categories a substance must belong to in order to qualify for inclusion on the candidate list.³³³ When comparing those two provisions, it can be argued that ESMA's powers are delineated by a larger amount of conditions, however, when looking at the actual conditions as such, it becomes apparent that the criteria of Article 28 Short Selling Regulation leave even more discretion to the Agency than ECHA has under Articles 57 and 59 of the REACH Regulation. This is because the criteria limiting ESMA's powers are much more vague and require a lot of balancing, for example in order to determine whether something indeed threatens the internal market or what a measure has to look like in order to 'significantly' tackle those threats. On the contrary, ECHA in performing its tasks, does not have that much leeway. It needs to stick to the sufficiently clear criteria for substance qualification under Articles 57 and 59 REACH Regulation. Therefore, it is inappropriate to conclude that the margin of manoeuvre left to ECHA goes beyond what would be allowed under the *ESMA Short-selling case*. ECHA is not conferred upon a 'very large measure of discretion'. This conclusion is even strengthened when considering that it is in the end always the Commission that takes the actual decision of authorising a SVHC on the internal market, whereas ECHA's decision only affects the applicants in terms of information requirements.³³⁴

³²⁶ *ibid* Art. 28(2)(a)-(b) and 28(3)(a).

³²⁷ *ibid* Art. 28(3)(b)-(c).

³²⁸ *ibid* Art. 28(4)-(5) and (10).

³²⁹ REACH Regulation, Art. 59.

³³⁰ *ibid* Art. 59(4).

³³¹ *ibid* Art. 59(6).

³³² *ibid* Art. 59(7)-(8).

³³³ *ibid* Art. 57.

³³⁴ *ibid* Art. 60.

For information requirements see for example: Arts. 7(2), 31(1)(c), 31(3)(b) or 33(1) and (2).

Next, as concluded in the previous chapter, ECHA also enjoys some decision-making powers when it comes to biocidal products. More specifically it needs to accept or reject applications for approval of an AS or its renewal,³³⁵ or for validation of Union authorisations or their renewals respectively.³³⁶ These decisions are conditioned upon a single criterion, namely the payment of a fee and leave thus no room for discretion to the Agency.³³⁷ Consequently, neither the traditional nor the updated the *Meroni* doctrine is breached. Moreover, ECHA is competent to decide on requests for technical equivalents or data-sharing.³³⁸ In both cases, ECHA needs to consider the information submitted in order to take its decision. There are thus no specific criteria guiding the Agency in its decision-making process. However, even under the strict *Meroni* requirements, those powers could arguably be acceptable, because it does not amount to the execution of ‘actual economic policy’. But here again, it depends very much on the exact reading of the 1958 judgment. In any case, as the Court has to stick to the information provided for by the applicants and can only decide to approve or reject the application,³³⁹ it is unlikely that ECHA has been transferred too much discretion under the BP Regulation and therefore the *ESMA Short-selling* requirements are met.

Finally, the same can be said with regard to ECHA’s decision-making powers under the CLP Regulation, which consist in approving a change of a chemical’s name.³⁴⁰ In essence what needs to be proven by the applicants is that, by making the chemical name publicly available, ‘the confidential nature of his business’ is seriously endangered.³⁴¹ Although this leaves the Agency with some room for discretion, only substances that fulfil the requirements of Part 1 Annex 1 are eligible for name substitution.³⁴² As the latter is again a rather technical assessment, taken together with the fact that the burden of proof as regards the confidentiality of the business being endangered is upon the applicant,³⁴³ the ECHA does not possess a lot of discretion. Whether it would also be in accordance with the traditional *Meroni* judgment is however

³³⁵ BP Regulation, Arts. 7(2) and 13(3).

³³⁶ *ibid* Arts. 43(3) and 45(3).

³³⁷ *ibid* Arts. 7(2), 13(3), 43(3) and 45(3).

³³⁸ *ibid* Arts. 54(3), 63(3) and 64(1).

³³⁹ *ibid*.

³⁴⁰ CLP Regulation, Art. 24.

³⁴¹ *ibid* Art. 24(1).

³⁴² *ibid*.

³⁴³ *ibid*.

questionable and depends on the latter's reading. In any case, the criteria seem to be sufficiently clear to justify compliance with *ESMA Short-selling*.

Hence, it can be concluded that, when looking at the scope of the delegated decision-making powers to ECHA only, the tasks relating to completeness checks as well as to the adoption of a Community Rolling Action Plan can be held to be compatible with the requirements of the traditional as well as the modified *Meroni* doctrine. This is because the ECHA is not empowered to exercise discretion. The same holds arguably true for the Agency's tasks of accepting applications for approval and for Union authorisations and their renewals within the context of the BP Regulation. For the remaining decision-making powers under the BP and the CLP Regulation, as well as the ECHA's tasks in the context of data sharing under REACH, compliance with the traditional *Meroni* limits is questionable, because on the one hand, the exercise of its tasks is not 'clearly defined' but on the other hand, the assessment ECHA has to conduct is very technical. It depends very much on whether the *Meroni* requirements are strictly interpreted or not. On the other hand, despite being circumscribed by sufficiently clear and precise criteria, a certain room for discretion is present with regard PPORD exemptions, the conducting of the compliance check, the examination of testing proposals and the decision to include a substance on the candidate list for authorisation. Hence, in those circumstances, the *ESMA Short-selling* case, as interpreted in the framework of this Thesis, would actually lead to ECHA's powers under the REACH Regulation being compatible with the redefined *Meroni* doctrine, even though, the anti-delegation doctrine in the traditional sense would have been infringed. However, the restriction of the scope of powers that can be delegated to agencies is only one part of the story. The second step would be to examine the way in which the ECHA is controlled when exercising its decision-making powers.

4.2. The control of the Agency

When it comes to the need for controlling EU agencies, it is adequate to distinguish between two different forms of supervision. Firstly, the control by the delegating authority as prescribed in *Meroni* needs to be addressed.³⁴⁴ In that regard, as the delegation of powers to agencies cannot be described as a traditional delegation, it is not sufficient to look at the extent to which the Commission is involved in the decision-

³⁴⁴ Case 9/56 *Meroni & Co, Industrie Metallurgische S.P.A. v. High Authority* [1957–1958] ECLI:EU:C:1958:7, 152.

making process only, but on the contrary, Member States' involvement is of importance as well.³⁴⁵ Secondly, instead of focussing on the control by delegating authorities, the Court in *ESMA Short-selling* focussed on the need for judicial review.³⁴⁶

Starting with the latter, the possibility for judicial review is since the adoption of the Lisbon Treaty secured by the inclusion of agencies in the group of bodies against which a claim can be brought before the CJEU.³⁴⁷ However, as is well known, the standing requirements before the CJEU for non-privileged applicants are very strict, requiring them to prove that they are either directly addressed by the decision, 'directly or individually concerned' or directly concerned in case of a regulatory act.³⁴⁸ However, the problems that might arise with regard to those standing requirements are not decisive for determining whether the *ESMA requirements* are fulfilled. In fact, the efficiency of judicial review of agency decisions is a whole new topic and its discussion would go beyond the scope of this Thesis. Suffice it to say that the possibility for judicial review of both ECHA decisions as well as Board of Appeal decisions³⁴⁹ is given and therefore the control aspect of the *ESMA case* is fulfilled.

In addition to this, it needs to be recalled that ECHA has its own Board of Appeal. However, as has been established beforehand, this body cannot be defined as being judicial *per se*, but is an administrative body that forms part and parcel of the Agency.³⁵⁰ Still, appeals to the BoA are of utmost importance. Therefore, it is interesting to notice that, first of all, the decision taken under the CLP Regulation cannot be appealed to the Board.³⁵¹ Moreover, even more importantly, the controversial power of ECHA to include a substance in the candidate list for authorisation cannot be brought before the in-house BoA either.³⁵² As it has been held that the act of defining a substance as being of very high concern constitutes a proper decision, this is unfortunate.

³⁴⁵ See section 2.1.

³⁴⁶ Case C-270/12 *The United Kingdom v. Council and European Parliament* [2014] ECLI:EU:C:2014:18, para 53.

³⁴⁷ Art. 263 TFEU; see also: Arts. 265, 267 or 277 TFEU.

³⁴⁸ Art. 263 TFEU.

³⁴⁹ REACH Regulation, Art. 94.

³⁵⁰ Steven Vaughan, *EU Chemicals Regulation: New Governance, Hybridity and REACH* (Edward Elgar Publishing), 72; Marcus Navin-Jones, 'Board of Appeal: Function, Powers and Decision-making' (ppt, Keller and Heckman LLP 2014) <www.khlaw.com/Files/20434_6.Marcus%20Navin%20Jones.pdf> last accessed 24 August 2017.

³⁵¹ CLP Regulation.

³⁵² REACH Regulation, Art. 91(1).

Turning now to the control requirements of the *Meroni* case, it can be first of all held that for the powers that were judged to be executive and therefore non-discretionary in nature, the situation with regard to control is not clear-cut. First of all, there is ECHA's power to establish a CoRoAP in accordance with the Article 51 procedure.³⁵³ Except for the case where no amendments are proposed to ECHA after the publication of its draft decision, both the MSC as well as the Commission may be involved in the decision-making process under different circumstances.³⁵⁴ This does not hold true when ECHA conducts the completeness check, where it acts completely on its own.³⁵⁵ However, even in those situations, there are some general provisions in the REACH Regulation that ensure that the Commission remains involved. First of all, it is the Commission that proposes ECHA's Executive Director.³⁵⁶ Secondly, under Article 117, ECHA has a general obligation to report to the Commission. In light of the non-discretionary nature of the powers just mentioned, the control mechanisms are sufficient in order to ensure that the *Meroni* judgment is complied with. The same holds true for the acceptance of applications for approvals or their renewals under the BP Regulation,³⁵⁷ or applications for Union authorisations or their renewals respectively,³⁵⁸ because in those circumstances the Commission always takes the final decision of actually approving the applications or granting the authorisations.³⁵⁹

For cases where discretion is obviously involved on the part of the ECHA, namely the inclusion of a substance in the candidate list, the examination of testing proposals and the execution of compliance checks, control is mostly ensured through both MSC and COM involvement, in line with the Article 51 procedure.³⁶⁰ The powers involved in granting a PPORD exemption form an exception in that regard. Surprisingly no control mechanisms are put in place under Article 9, which is why it clearly breaches the traditional *Meroni* doctrine. However, even for the former three situations, where the

This is probably the case because, the REACH Regulation treats it as an opinion by the ECHA, and not a solid decision on its own.

³⁵² Case T-96/10 *Rütgers Germany GmbH v. ECHA* [2013] ECLI:EU:T:2013:109, para 34.

³⁵³ REACH Regulation, Art. 44(2).

³⁵⁴ *ibid* Art. 51.

³⁵⁵ *ibid* Art. 20(2).

³⁵⁶ *ibid* Art. 84(1).

³⁵⁷ BP Regulation, Arts. 7(2) and 13(3) .

³⁵⁸ *ibid* Arts. 43(2) and 45(3) .

³⁵⁹ *ibid* Arts. 9, 14(4), 44(5) and 46(4).

³⁶⁰ REACH Regulation, Arts. 40, 41 and 59 .

ECHA already enjoys discretion, those control mechanisms do not seem to be sufficient considering the mostly very strict interpretation of the *Meroni* conditions as well as the Court's opinion that only in case of 'clearly defined executive powers' would control be strict enough. This is especially the case because there is still the possibility for ECHA to adopt a decision on its own in case of lack of proposed amendments.³⁶¹ The fact that an Article 59 decision is often only interpreted as being a first step towards the adoption of the final decision by the Commission does not change this conclusion.

Lastly, when it comes to ECHA's decision making powers in the field of establishing a technical equivalence and data-sharing under the BP Regulation,³⁶² its power to accept the application for a request of change of name under the CLP Regulation,³⁶³ or under the data-sharing provisions of the REACH Regulation respectively,³⁶⁴ no specific involvement of Member States or the Commission is foreseen. In light of the uncertainty existing about their compliance with the *Meroni* requirements relating to the scope of powers, it is rather unlikely that those powers would be allowed under the traditional non-delegation doctrine.

4.3. Conclusion

Considering the foregoing, it can be argued that under the traditional *Meroni* doctrine, ECHA's powers to conduct a compliance check, to accept or reject the request for testing proposals as well as its task of defining a substance as being potentially very dangerous and therefore as to be included in the candidate list for authorisation would not be allowed. This is because there is both an infringement of the prohibition to delegate discretionary powers to agencies as well as a lack of sufficient control in all possible circumstances. On top of that, some of the Agency's tasks under the REACH, CLP and BP Regulation are at least on the borderline of what could be allowed. On the other hand, under the *Meroni 2.0.* doctrine, it can reasonably be argued that all of the powers enjoyed by ECHA are circumscribed by sufficient

³⁶¹ *ibid* Art. 51(3).

³⁶² BP Regulation, Arts. 54(3), 63(3) and 64(1).

³⁶³ CLP Regulation, Art. 24.

³⁶⁴ REACH Regulation, Arts. 27(6) and 30(2)-(3).

criteria and conditions as well as being susceptible to judicial control by the CJEU and therefore comply with the *ESMA* requirements.

Hence, even though the Court formally upheld the *Meroni* doctrine in the *ESMA Short-selling* case, the change of wording indeed affects the legitimacy of the decision-making powers of the ECHA. It remains therefore to be seen whether the Court will continue along the lines of the *ESMA* case or whether it will go back to the strict non-delegation doctrine, which would lead to certain aspects of ECHA's powers going beyond the scope of the permissible.

Conclusion

This Thesis was construed around the discrepancies between the formal adherence to the strict non-delegation doctrine as established in *Meroni v. High Authority* on the one hand and the delegation of an increasing scope of powers to EU agencies and the apparent adjustment of the *Meroni* doctrine in the *ESMA Short-selling* case on the other hand. The focus was on the European Chemicals Agency, as the first agency to be delegated a wide range of powers, including decision-making ones, in each step of the risk regulation process. In trying to discover whether the delegation of powers to the ECHA is still compliant with both the *Meroni* doctrine in the traditional sense as well as the updated version of it as established in *ESMA Short-selling*, several issues have been discussed and problems have been highlighted.

In order to be able to reply to the research question, it was necessary to provide the reader with some background information about both the agency phenomenon in the European Union as well as the practice of delegating powers to relatively independent bodies, such as agencies. All in all, this general analysis of the *agencification* of the EU executive and the associated non-delegation doctrine revealed that the delegation of powers to EU agencies is a field of law that is above all characterised by a lot of obscurity and a lack of clarity.

This is illustrated first and foremost by the lack of clear and uniform definitions of concepts such as ‘agency’ or ‘delegation’. In that regard it could be concluded that, despite the lack of a uniform understanding of those two concepts, the ECHA can be identified as an agency and its empowerment can reasonably be defined as a delegation. Starting with the former, the indications provided for by both the Commission as well as academics such as Griller and Orator were used to come to this conclusion. With regard to the latter, it was established that the empowerment of agencies cannot be described as a delegation in the traditional sense, taking into account that explicit delegation norms are lacking and that there is often no direct transfer of powers from the Commission to agencies. However, in the end, in light of the Court’s reasoning in *ESMA Short-selling*, it is still possible to reasonably argue that a *de facto* delegation of powers to EU agencies takes place and that the *Meroni* doctrine can be applied to the agency phenomenon in the EU.

Next, this obscurity can also be found in the case law of the CJEU, which, by the use of descriptions such as ‘clearly defined executive powers’ as the opposite of ‘discretionary powers’, or the often cited not ‘very large measure of discretion’ leaves a lot of room for interpretation and can therefore not be uniformly applied. As the criteria relating to the scope of powers to be delegated are arguably the most significant ones in both *Meroni* as well as *ESMA Short-selling*, this vagueness is very unfortunate and cannot be remedied by the second set of criteria relating to the control of the Agency by either Member States and the Commission or the Court respectively. Indeed, next to having brought about more uncertainty when it comes to the actual limits that agencies’ powers need to stick to, the *ESMA Short-selling* case also seems to have restarted the debate about the relevance of control and accountability mechanisms. This goes as far as to lead some academics to translate the requirements related to the need for supervision and judicial review in *Meroni* and *ESMA Short-selling* respectively into a more general requirement of accountability. In their opinion, the presence of sufficient accountability mechanisms would remedy for the delegation of more discretion to EU agencies. Even though this aspect of the agency debate is not to be neglected, it would have gone beyond the scope of this Thesis and does require further research.³⁶⁵

This uncertainty governing the agency debate makes a clear and unambiguous analysis of ECHA’s powers very difficult. Nevertheless it was proven that, in light of the important and far-reaching decisions ECHA is able to take under the REACH, CLP and BP Regulation, it can indeed be defined as a decision-making agency. In general, ECHA’s decision-making powers come in at the registration, evaluation as well as the authorisation stage under the REACH Regulation, the approval and authorisation stages under the BP Regulation, as well as the hazard communication stage under the CLP Regulation. Without going into detail about all of the powers ECHA enjoys once again, there are especially four situations that, due to the discretionary judgement ECHA is able to make as well as the lack for sufficient and continuous control mechanisms, are quite clearly in breach of the traditional *Meroni* doctrine, namely the power to decide on the additional conditions and time limits when granting an PPORD

³⁶⁵ Roland Van Ooik, ‘The Growing Importance of Agencies in the EU: Shifting Governance and the Institutional Balance’ in DM Curtin and RA Wessel, *Good Governance and the European Union. Reflections on concepts, institutions and substance* (Intersentia 2005), 145.

exemption, the powers involved in conducting a compliance check, the power concerning the proposal for testing on vertebrates as well as the one to decide on the inclusion of a substance in the candidate list for authorisation. On top of that, considering the Court's recent statements confirming the broad discretion ECHA enjoys in deciding about the adding of a substance to the candidate list in cases such as *Rütgers*, at least ECHA's decisions to include substances in the candidate list for authorisation provide for a potential of contradicting the non-delegation doctrine as modified in *ESMA Short-selling*. However, a deeper look into the specific circumstances of the case revealed that first of all the underlying claims were quite different, in that the applicant in *ESMA* specifically claimed a violation of the *Meroni* doctrine, whereas the issue at stake in *Rütgers* was the breach of the principle of proportionality. This is of utmost importance because where the principle of proportionality is invoked, the Court generally keeps its involvement to a minimum. On top of that a comparison of Articles 28 of the Short Selling Regulation and 59 of the REACH Regulation also brought about the awareness that actually the conditions circumscribing the powers of the ESMA, which as we should know by know were held to be compatible with *Meroni*, are more open than those delineating ECHA's powers. Taken together with the fact that judicial review is nowadays generally possible when it comes to agencies' acts, it can therefore be argued that all of the powers of the ECHA can reasonably be held to be in compliance with the updated *Meroni* doctrine.

Finally, in light of the foregoing it can be concluded that ECHA's decision-making powers fall within the scope of the limits established by the *Meroni* requirements as modified in *ESMA Short-selling*. On the contrary, when it comes to ECHA's decision-making powers concerning PPORD exemptions, compliance checks, testing proposals and substances that are added to the candidate list for authorisation, the Agency's powers go probably beyond the traditional limitations of delegation to agencies as established in *Meroni*. In that regard, the *ESMA Short-selling* case indeed seems to have opened the door to the transfer of a certain degree of discretionary powers to EU agencies. In light of the need for more effective and uniform decision-making in an ever-growing European Union, this development is to be welcomed. It remains to be seen how the Court will deal with similar cases in the future.

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